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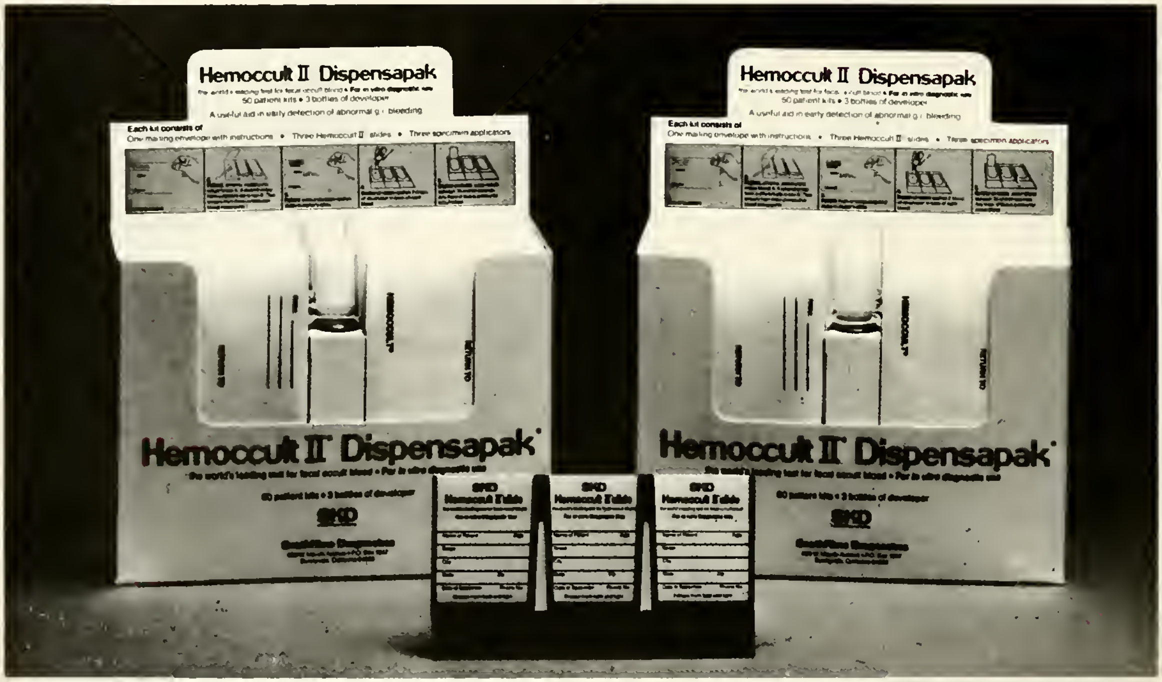

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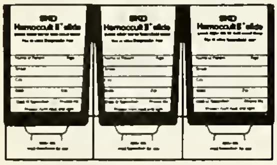

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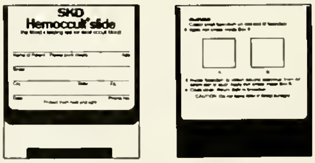

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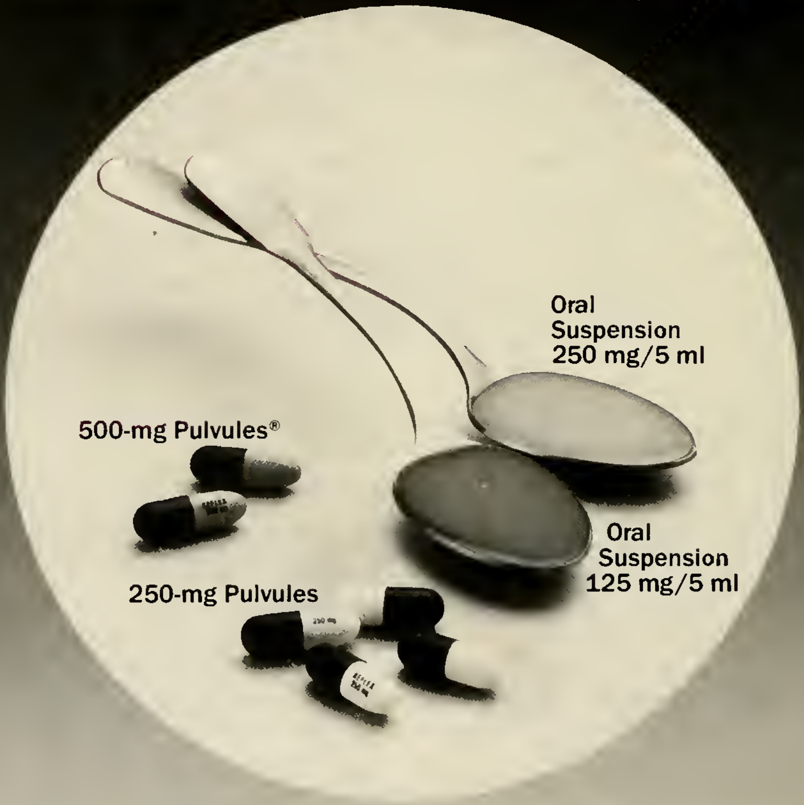

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SCIENTIFIC ARTICLE

Salmonella Choleraesuis Endocarditis

Jeffrey I. Cohen, M.D.

SALMONELLA endocarditis is rare. The majority of reported cases have been caused by *S. choleraesuis*, *S. typhimurium*, and *S. enteriditis*. The disease often presents acutely and may be complicated by valvular perforation, atrial thrombosis, pericarditis, pancarditis, and myocardial abscess. Most cases of salmonella endocarditis are fatal. Successful antibiotic treatment of *S. choleraesuis* has been reported only once in the literature.[1] The following report describes a second case with a favorable outcome and investigates the rationale for the choice of antibiotics.

Case Report

A 25-year-old black woman was admitted to the hospital with fever and loss of vision in the left eye. The history and physical exam showed evidence of a left central retinal artery occlusion and a new heart murmur. Blood cultures drawn the day before admission grew *Salmonella choleraesuis* sensitive to ampicillin, chloramphenicol, trimethoprim-sulfamethoxazole, gentamicin, and tobramycin. Subsequent blood cultures (after treatment) were negative and a stool culture was negative for Salmonella.

Comment — *Salmonella choleraesuis* was first described in 1885 by Salmon and Smith as the hog cholera bacillus, and the first report of human infection in the United States was reported by Longcope in 1902.[2] Adults infected with *S. choleraesuis* often have bacteremia with secondary localized infections such as muscle abscesses, mycotic aneurysms, osteomyelitis, or meningitis. *S. choleraesuis* infections have a fatality rate that is five to six times higher than infections due to other salmonella serotypes.[3] There have been 10 previous case reports of *S. choleraesuis* endocarditis during the antibiotic era.[1, 4-11] Nine of the 10 cases were fatal; the only survivor was treated with penicillin and polymyxin B.

The patient's hospital course is depicted in figure 1. The patient was begun on a combination of various antibiotics and on the second hospital day an echocardiogram showed mitral valve thickening and mitral valve prolapse. No evidence of mitral regurgitation or intracardiac shunt was noted; however, fluoroscopy showed mitral valve annulus calcification. When blood culture results returned, treatment was changed to ampicillin (with acetaminophen). On the fourth hospital day a hemorrhagic lesion was noted on an index finger and a splinter hemorrhage was found. On the eighth hospital day, because of persistent fever, ampicillin was stopped and intravenous trimethoprim-sulfamethoxazole was begun. On the 10th day an echocardiogram showed a mitral valve vegetation, probable mitral valve ring abscess, pericardial effusion, and a possible tricuspid valve vegetation (similar findings were noted five days later). On the 20th day the patient was still febrile, trimethoprim-sulfamethoxazole and acetaminophen were stopped, and ampicillin and chloramphenicol were begun. Her temperature returned to normal the following day and she remained afebrile thereafter.

Comment — While salmonella are often sensitive to many antibiotics *in vitro*, these *in vitro* tests do not correspond to an *in vivo* response. Four antibiotics — ampicillin, amoxicillin, chloramphenicol, and trimethoprim-sulfamethoxazole — are effective against salmonella *in vivo*. Salmonella are often sensitive to other antibiotics including aminoglycosides and cephalosporins *in vitro*, but these drugs are ineffective *in vivo*. *In vitro* sensitivity testing is useful, however, in determining whether a salmonella isolate is resistant to one of the four drugs listed above.

Along with antibiotic therapy for salmonella bacteremia, most authors stress the importance of determining sites of localized infection. These include aortic aneurysms, heart valves, and myocardial abscesses. Radionuclide scanning, ultrasonography, echocardiography, arteriography, and cardiac catheterization have all been used to identify lesions involving the cardiovascular system. If an infected atherosclerotic aneurysm or heart valve is found, most authors recommend treatment with intravenous antibiotics, followed by surgical removal of the infected site and replacement by a graft or prosthesis.

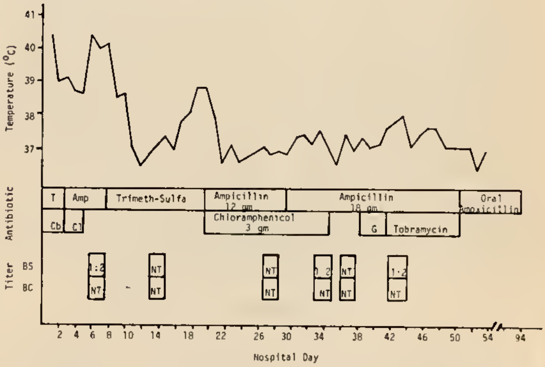

Figure 1. *Hospital course. BC = Bactericidal, BS = Bacteriostatic, NT = No titer, T = Tobramycin, G = Gentamicin, Cb = Carbenicillin, Cl = Chloramphenicol, Trimeth-Sulfa = Trimethoprim-Sulfamethoxazole, Amp = Ampicillin.*

From the Department of Medicine, Duke University Medical Center, Durham 27710.

Acknowledgment. The author is indebted to Dr. E. G. Estevez for his help in devising the time-killing curves.

On the 35th day, pancytopenia and reticulocytopenia were noted, chloramphenicol was stopped, and gentamicin was begun (later changed to tobramycin because of a skin rash). On the 36th day an echocardiogram showed no vegetations or abscess; subsequent echocardiograms were unchanged. On the 51st day intravenous antibiotics were stopped (four weeks after defervescence) and oral amoxicillin was begun. Two days later she was discharged. Oral amoxicillin was stopped after six weeks, and she remains asymptomatic six months after all antibiotics have been stopped. Serum bactericidal activity was never achieved and bacteriostatic titers of only 1:2 were obtained with various combinations of antibiotics (see figure 1).

Comment — Schlicter and McLean studied patients with endocarditis and measured serum inhibitory concentrations as the highest dilution of the patient's serum that would inhibit growth of the patient's organism.[12] This has been modified to include serum bactericidal titers, the dilution of the patient's serum (while on antibiotics) that kills the patient's organism *in vitro*. Current recommendations (for streptococcal endocarditis) suggest that antibiotics be adjusted to maintain a peak bactericidal concentration of ≥1:8 against the patient's organism.[13]

The patient presented above had a successful outcome despite failure to achieve adequate bactericidal activity against the organism. In a review of studies of serum bactericidal concentrations in bacterial endocarditis, Coleman et al found that none of the 17 studies showed a significant association between serum bactericidal concentrations of ≥1:8 and survival or bactericidal cure. They noted, however, that "each of the studies had an insufficient sample size to confidently exclude a false-negative result."[14] In order to determine why this patient responded to ampicillin and chloramphenicol, despite failure to achieve serum bactericidal titers, the patient's organism was tested further.

Methods

The interaction between the patient's bacterial isolate and the antibiotics used was studied *in vitro* by determining time-killing curves.[15] Antibiotics were prepared at concentrations that approximated peak serum levels obtainable by intravenous injection. The patient's strain of *S. choleraesuis* was incubated to turbidity and then diluted in brain heart infusion broth to a final concentration of 10^5 colony-forming units/ml. The organism was incubated at 35°C with (1) ampicillin and chloramphenicol, (2) trimethoprim and sulfamethoxazole, and (3) sterile water (control). The final concentrations of antibiotics were ampicillin 28 mcg/ml, chloramphenicol 10 mcg/ml, trimethoprim 9 mcg/ml, and sulfamethoxazole 100 mcg/ml. At 0, 2, 4, 6, 8, and 24 hours samples were withdrawn, diluted, and placed on blood agar plates. Colonies were counted after incubation for 24 hours.

Results

Figure 2 shows a plot of the time-killing curves obtained with the patient's isolate and the two antibiotic combinations. Initially there was a decline in the number of bacteria with the ampicillin-chloramphenicol combination; however, with time there was a marked increase in the number of bacteria. This may have been due to inactivation of antibiotic during incubation or selection of resistant organisms. In contrast, with the trimethoprim-sulfamethoxazole combination bacterial growth was only slightly diminished when compared with the control.

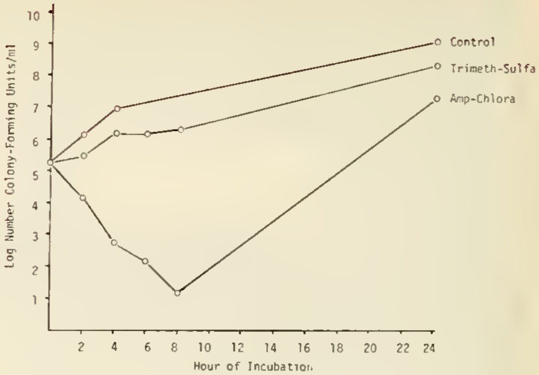

Figure 2. *Time-killing curves. Trimeth-Sulfa = Trimethoprim-Sulfamethoxazole, Amp-Chlora = Ampicillin-Chloramphenicol.*

Discussion

This patient had *S. choleraesuis* endocarditis and initially defervesced with trimethoprim-sulfamethoxazole. Subsequently, however, she had a relapse which responded to therapy with ampicillin and chloramphenicol. Analysis of serum bactericidal concentrations was not helpful in determining antibiotic therapy in this case. Instead, an alternative approach was used — measurement of the *rate* of killing of the patient's organism by two antibiotic combinations. Analysis of time-killing curves using the patient's bacterial isolate and the two antibiotic regimens showed that ampicillin-chloramphenicol resulted in a decline in the number of bacteria; trimethoprim-sulfamethoxazole only diminished the rate of growth.

These experiments thus helped to explain *in retrospect* why one antibiotic combination succeeded while another failed. In treating this patient the physicians tried a series of antibiotics known to be effective against salmonella *in vitro* and *in vivo*. While specialized tests (analysis of serum bactericidal concentrations) were tried, other clinical and laboratory signs (defervescence and fall in white blood cell count) were used in monitoring antibiotic therapy.

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SCIENTIFIC ARTICLE

Disaster Plan Implementation: Tornadoes Strike Eastern North Carolina

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• *Pitt County Memorial Hospital put its disaster implementation plan into action when tornadoes struck eastern North Carolina on March 28, 1984, killing 44 people and injuring over 800.*

WITH a tornado warning in effect, at approximately 9:25 p.m. on the evening of March 28, a tornado touched down initially in the Scuffleton community in Greene County, southwest of Pitt County, and essentially remained on the ground throughout its course through the southern areas of the county. Its course covered approximately 22 miles through more densely populated areas around Ayden, Simpson and the Portertown section, south of Greenville. The path cut by the tornado ranged from one-fourth to one-half mile wide.

Pitt County is served medically by Pitt County Memorial Hospital (PCMH), a 570-bed institution affiliated with the East Carolina University School of Medicine. It is a Level II Regional Trauma Center.

Initial Field Response

Area rescue squads began responding to calls for help at approximately 9:25 on the evening of the 28th, almost immediately after the tornado had struck. Local volunteer rescue squads from the counties of Pitt, Edgecombe, Greene and Lenoir all responded to the call, as well as rescue vehicles from the city of Greenville. It was initially very difficult to determine the extent of the disaster because of the windy, rainy weather and the fact that it was night. This disaster differed from others in Pitt County and across the state and nation in that there was no localized, circumscribed disaster scene. Victims were scattered over a 10-to-12-mile radius.

This lack of a well-defined disaster site as well as the weather conditions and darkness led to one basic change in the way the disaster was handled. Normally, in any local disaster a physician-nurse triage team is transported immediately by the local sheriff's department to the field from Pitt County Memorial Hospital. On the scene, they set up a field triage headquarters and immediately begin triaging patients for transport to the hospital. This system has worked exceedingly well in disasters that have occurred in Greenville during the last year: one in March 1983, when leaking gas from a clothes dryer exploded in a Greenville apartment complex, killing one 19-year-old East Carolina University student and injuring more than a dozen others; another in April 1983, when a school bus overturned and injured 65 children, five of them seriously.

The rescue personnel involved in the tornado disaster were all basic EMTs or EMT-Intermediates. With the lack of a physician-nurse triage team in the field, triage was carried out by senior EMTs on the scene according to protocols developed by the Department of Emergency Medicine at East Carolina University School of Medicine/ Pitt County Memorial Hospital. The triage efforts by these EMTs went exceedingly well, with a majority of the patients with life-threatening but salvageable injuries being transported to the hospital first.

Internal Response

At 9:00 p.m. the emergency department at Pitt County Memorial Hospital was relatively quiet. By 9:30 p.m., it was evident that a tornado had struck the southern end of the county, although the extent of damage and personal injury was not known. It took 10 to 15 minutes before the first rescue squads arriving at the various scenes of the disaster relayed an approximation of the damage. At this point the emergency attending physician on duty immediately activated the hospital's internal disaster plan: machinery was set into action to rapidly call many of the physicians as well as nursing and other personnel to the hospital. Within 30 minutes, at least 30 physicians and over 500 hospital employees from various departments including nursing, social services, respiratory therapy, administration, central supply and the cafeteria arrived at the hospital.

As physicians arrived in the emergency department, they reported to the physician coordinator in the emergency department who assigned them according to their specialty and skills to various areas within the department. This same procedure was followed with nursing personnel, who reported to a nursing supervisor in the emergency department. Security maintained and policed the area and directed family and friends to the cafeteria. A temporary morgue was set up immediately adjacent to the hospital morgue.

The first patients to arrive at the hospital at about 9:30 p.m. were actually brought directly to PCMH in private cars by friends, relatives and family. Rescue squads began

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transporting their first victims to the hospital by 9:45 p.m. Between 10 p.m. and 2 a.m. the hospital's emergency department handled more than 150 injured individuals and admitted 29 people. Many of the latter were in critical condition. Four people died where they were struck that evening; a fifth individual was found dead the following morning. Four more patients died in the hospital, three in the emergency department and one in the operating room.

Patients had two methods of access to the emergency department. The first was through the ambulatory entrance to the department and this was used only by those patients who were brought to the hospital by their families in private automobiles. All subsequent admissions to the hospital by rescue squad came in through the rescue entrance. Physician-nurse teams skilled in triage were placed at both entrances to the emergency department and patients were triaged as they entered. These triage teams had some idea of what they were going to receive because the rescue squads had called in ahead of time over the radio giving their assessment of their patients' injuries.

As patients were triaged at the entrance to the emergency department they were assigned to areas in the department corresponding to the seriousness of their injuries and the stability or instability of their vital signs. The hospital's internal disaster plan assigns physicians, nurses and other ancillary personnel to the various areas of the department to which patients are sent after being triaged.

As patients entered the ED they were given an identification band and this information was then transferred to a master list. Patients' families and friends were diverted from the emergency department to the hospital cafeteria where members of social services and hospital administration worked with them throughout the night. By 1:00 a.m. approximately 500 friends and relatives were waiting in the cafeteria.

Later, as patients were being discharged from the emergency department or admitted to the hospital, an open line of communication was set up between the emergency department and the cafeteria. As a patient was ready to be discharged, the staff in the cafeteria would be contacted and the family would be brought to the emergency department waiting room to talk with the patient and the physician in attendance.

Within two hours after the tornado touched down, more than 100 victims had been admitted to the emergency department. Because of this heavy patient load we had to transfer patients who were more ambulatory to other areas of the hospital. As had been prearranged in PCMH's disaster plan, the ambulatory medical surgical unit was used and about 15 patients under the care of three physicians and several nurses were triaged there. One of the medical wards was partially cleared and it, too, was used for ambulatory patients.

No inpatients had to be discharged from the hospital. As patients were evaluated and their needs determined, phlebotomists stationed in the area drew blood for typing. Fortuitously, there was no severe strain on the blood bank. These patients then were transported when appropriate to the Department of Radiology which is contiguous to the emergency department. Other patients underwent portable x-ray procedures in the emergency department. Eight operating room suites were held in readiness during the disaster, and four of them were used at one time. The renal transplant team was working during the entire disaster on a previously scheduled transplant operation.

Problems and Recommendations

Several problems were noted during the course of this disaster, most of which were in some way dependent upon the severity and the size of the event. Almost two and one-half times as many injured patients were treated during this disaster as in any prior emergency situation in the hospital's history.

The initial problem was one that no one could do anything about: there was no circumscribed disaster site. Therefore, our normally functioning plan to send a physician-nurse triage team to the field proved useless. However, the EMT personnel trained in triage techniques handled on-site triage more than adequately. Another problem at the scene which added difficulties was the fact that many phone lines were down in the area.

One of the major difficulties in the emergency department with such a large number of patients was that of identifying and tracking patients. Patients were entering the hospital at two different entrances and therefore were receiving identification tags at two sites. This made compilation of a master list of patients in the emergency department somewhat cumbersome.

As the disaster progressed and as more ambulatory patients were by necessity moved to other areas of the hospital (including to x-ray, to the ambulatory medical surgical unit, to the regular medical floors by admission, and to the operating room), keeping track of patients' whereabouts became extremely difficult. We have no ready solutions for this situation, but some means of identifying and keeping track of a patient throughout the disaster is essential. We find our ''area assignment'' method effective in efficiently assigning personnel and in categorizing patients. However, we have found in previous disaster situations that more ambulatory patients tend to be left unattended while more severely injured patients are being treated.

Because of the large numbers of medical and nursing personnel on the scene the night of this disaster, we found it appropriate to do a great deal of one-on-one assignments, that is assigning one nurse and one physician to one or two patients. This system seemed to work extremely well because the physician-nurse team tended to follow through on a patient's care in a much more thorough way than through general area assignments.

Another transient problem arose with the Blood Bank. When the disaster began our Blood Bank had only ten units of O negative universal donor blood on hand. Our pathologists wanted to save this blood for those patients requiring immediate transfusion(s). However, patients were not typed rapidly as they entered the hospital, so initially obtaining type-specific blood was rather delayed. This situation was rectified as the disaster progressed: the pathologists stayed near the triage area at the door, and as severely injured patients arrived, phlebotomists were immediately assigned to draw the patient's blood for typing, resulting in the more immediate availability of type-specific blood.

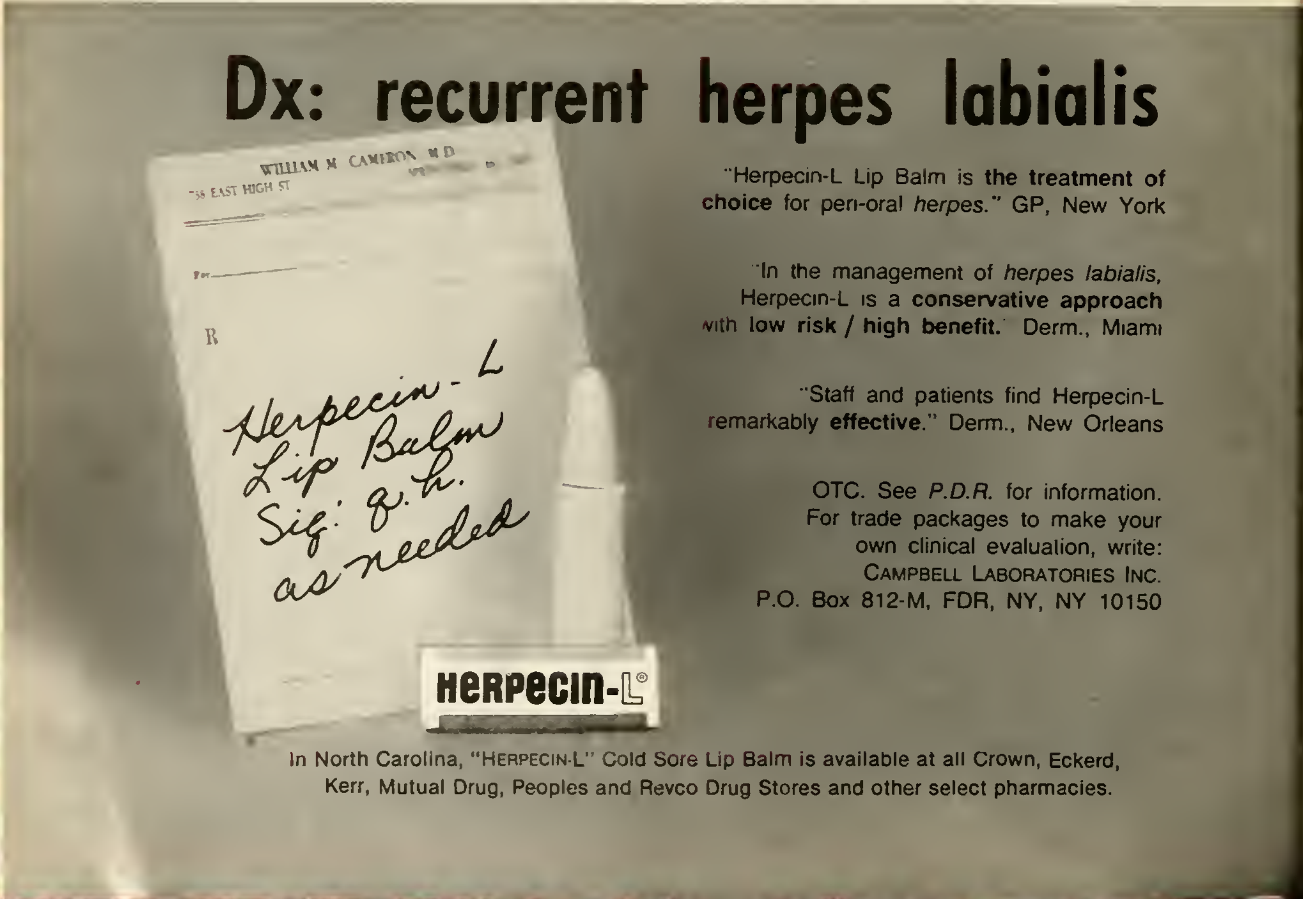
Another problem that arose during this disaster was the scheduling of x-rays. Critically ill patients in the emergency department who needed x-rays immediately underwent portable procedures without difficulty. However, the bulk of the patients who were judged able to be transported to x-ray were not adequately differentiated according to how urgent their need for x-rays really was. We acutely felt the need for some system of assigning patients for x-rays so that the more critically injured patients were served first.

Handling of patients' families, friends and relatives in the hospital cafeteria (more than 500 individuals) went extremely well during this disaster. The Department of Patient and Family Services at PCMH was primarily responsible for this aspect of our disaster plan. Two problems were noted, however. First, there were not enough outside telephone lines in the cafeteria for the families to phone other relatives and friends in the community, which created some anxiety among those waiting. Second, there were problems with communication between the cafeteria and the emergency department as patients were ready for release, or if general information concerning patients needed to be communicated. Two systems were tried: initially, an open phone line between the two locations was used, which was unfeasible; later, a walkie-talkie system was employed with some success.

Conclusion

Our hospital's response to the disaster of March 28 was gratifying. Patient care was excellent and expeditious. However, as in any such situation, many areas for change were noted. While a certain amount of flexibility and "fly by the seat of your pants" behavior is necessary and probably essential in a disaster situation, none of this can or will take the place of adequate disaster planning. Pitt County Memorial Hospital is presently revising its disaster plan to effect improvements in the areas noted above.

It has been said that we experience God's love most fully through the expression of love we share with one another. The citizens of eastern North Carolina were indeed witness to the abundance of God's tender mercies on and since March 28, 1984.



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SCIENTIFIC ARTICLE

The Impact of Low Birth Weight on North Carolina Neonatal Mortality 1976-1982

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INFANT mortality is an important problem in both the United States and North Carolina. In 1978 the United States ranked 17th among industrialized Western nations in terms of low infant mortality,[1] and the State of North Carolina has one of the highest infant mortality rates in the United States.[2] Neonatal mortality (deaths between birth and 28 days of age) is a large component of infant mortality, accounting for 69 percent of 1980 North Carolina infant deaths.[3] Of these neonatal deaths, 63 percent occurred under one day of age and 86 percent occurred under 5 days of age.

One of the most important factors contributing to neonatal death is low birth weight.[4-6] In North Carolina in 1980, 71 percent of infants weighing less than 1000 grams died before 28 days of age compared with 0.2 percent of infants weighing over 2500 grams. Therefore, in comparing overall neonatal mortality rates between areas, it is important to control for differences in birth-weight distributions before drawing conclusions about the relative levels of mortality risk. This is very similar to standardizing or adjusting crude death rates for differences in age distribution. Guyer et al[1] recently standardized the Massachusetts neonatal mortality to the birth-weight distribution of Sweden and found that the resulting rate was 3 percent lower than that of Sweden, compared with a crude (unstandardized) Massachusetts neonatal death rate 58 percent higher than that of Sweden. In this paper we will compare North Carolina neonatal mortality with that of the United States in a similar manner, and assess the contribution of changing birth weight to neonatal mortality trends in North Carolina since 1976.

Method

The primary statistical method used in this study is birth-weight standardization by the direct method. In this calculation, birth-weight-specific neonatal mortality rates are weighted according to a hypothetical or "standard" distribution of birth weights. For example, multiplying the North Carolina death rates for each birth-weight category by the number of births expected if North Carolina had the same percent distribution of births by weight as the United States would yield a certain number of expected neonatal deaths. Computing an overall neonatal mortality rate using this expected number of deaths allows assessment of how much birth-weight distribution contributes to the higher overall neonatal mortality observed in North Carolina.

Neonatal deaths by birth weight are derived annually in North Carolina by automated and manual matching of each infant death certificate to the infant's birth certificate, from which birth weight and other infant as well as maternal information is obtained. Reports are received for events occurring in surrounding states that involve North Carolina residents, so that virtually all North Carolina resident neonatal deaths are included.

Birth weight is more than just a measure of grams. "Since birth weight serves as an intermediate outcome for many variables associated with infant mortality, birth weight can be viewed as a summary measure of the effect of these social and demographic risk factors."[7] Low-weight infants include those born too early (low gestational age) as well as those born too small due to intrauterine growth retardation. Low-weight infants are highly susceptible to a variety of life-threatening conditions. Although a combined measure of gestational age and birth weight might be the most appropriate indicator of prematurity, there is considerable rationale for focusing on birth weight as a single outcome measure. Birth weight alone has been shown to explain the variance in neonatal mortality almost as well as a combined index of gestational age and birth weight. Furthermore, vital statistics data on gestational age have been less reliable than the birth weight data, and nonresponse is high.[7] While greater birth weight may not prevent problems such as congenital anomalies, and very heavy babies may have special problems of their own, in most cases birth weight is a very good measure of survival potential.

Wilcox and Russell[8] have suggested that standardizing neonatal mortality for birth weight is biased against the population with higher birth weights. For example, the standardized neonatal mortality rate of the population with lower birth weights will be understated if the standardization is based on the birth-weight distribution of the population with higher birth weights. Their argument assumes that the schedule of weight-specific mortality weights of a population is primarily a function of the mean birth weight, and that increasing the mean birth weight (as is hypothetically done in standardization) would necessarily involve a corresponding shift in the weight-specific mortality rates.

From the Division of Health Services, Department of Human Resources, Raleigh 27602.

Table 1

Standardization of North Carolina's Neonatal Mortality Rate (NMR) to the Birth-Weight Distribution of the United States in 1980*

	North Carolina Actual				United States	North Carolina Expected		
Birth Weight in Grams	No. of Live Births	% of Live Births	No. of Neonatal Deaths	Neonatal Deaths per 1000 Live Births	% of Live Births	No. of Live Births	No. of Neonatal Deaths	Neonatal Deaths per 1000 Live Births
≤ 1000	611	0.72	432	707.0	0.54	457	323	
1001-1500	637	0.75	94	147.6	0.61	515	76	
1501-2000	1259	1.49	55	43.7	1.32	1116	49	
2001-2500	4204	4.98	61	14.5	4.37	3691	54	
≥ 2501	77770	92.06	188	2.4	93.16	78702	190	
Total	84481		830	9.8		84481	692	8.2

* Crude N.C. NMR (actual) is 9.8 per 1000 live births; standardized NMR (expected) is 8.2 per 1000 live births. The 1980 United States crude NMR is 8.5 per 1000 live births.

Note: A few North Carolina births (26) and neonatal deaths (14) of unknown birth weight have been allocated to birth-weight categories according to the percent distribution of those with known birth weight.

Thus they suggest it is not reasonable to increase birth weights via standardization and at the same time hold mortality rates constant. To the extent that the weight-specific mortality rates of a population are determined by biology, medical care, and other factors that might not change with an increase in the mean birth weight, the magnitude of the bias that they propose would be reduced. In any case, adjusting the standardized rates in the present paper for this possible bias would not alter any of the major findings or conclusions.

Results

Comparison with the United States

In 1980 there were 830 neonatal deaths in North Carolina out of 84,481 live births for a rate of 9.8 neonatal deaths per 1000 live births. United States data for 1980, the latest available, show a crude neonatal death rate of 8.5,[9] which is 13 percent lower than the North Carolina rate. If, however, we assume that North Carolina births had the same weight distribution as United States births, a different picture emerges (table 1).

In North Carolina 7.9 percent of 1980 births were below 2501 grams, compared to 6.8 percent in the United States. If North Carolina had experienced the same birth-weight distribution as the United States, 932 fewer infants of low birth weight would have been born in North Carolina in 1980. Applying the United States percent distribution by weight to the 84,481 North Carolina births in 1980 and then applying the North Carolina weight-specific neonatal death rates to these births results in 692 expected neonatal deaths. Thus if the North Carolina birth-weight distribution in 1980 had been the same as that in the United States, 138 fewer neonatal deaths would have occurred. The North Carolina neonatal mortality rate would then be 8.2 rather than 9.8, a 16.3 percent reduction and below the U.S. rate of 8.5 rather than higher as actually occurred.

We conclude that neonatal mortality is higher in North Carolina than in the United States because of a less favorable birth weight distribution and, in fact, weight-specific neonatal death rates are on the whole lower in North Carolina.

Neonatal Death Rates by Race

Standardizing the North Carolina neonatal mortality rate in the manner shown above does not take into account that the percent of nonwhites in North Carolina is higher than that in the United States. On the average, nonwhites have a substantially higher percent of low-weight births than whites. If one assumes that it is not reasonable for nonwhites in North Carolina to achieve the same birth-weight distribution as the U.S. average in the near future, then the approach of doing race-specific standardization would be appropriate. In North Carolina the white and nonwhite neonatal mortality rates in 1980 were 8.1 and 13.5, compared with United States rates of 7.5 and 12.5. If North Carolina whites and nonwhites had the same birth-weight distributions as their white and nonwhite counterparts in the United States, and there were no changes in the North Carolina race-weight-specific neonatal death rates, the 1980 North Carolina white neonatal mortality rate would be 7.5 and the nonwhite rate would be 12.0. Thus, even when each race is considered separately, the higher North Carolina neonatal death rate can be attributed entirely to lower birth weights.

A very interesting finding that emerges from this race-specific analysis is that 1980 North Carolina nonwhite weight-specific neonatal death rates were *lower* for every weight category than the comparable white rates. This was also true in North Carolina for 1981, and other studies have consistently shown substantially lower nonwhite neonatal mortality rates for birth-weight categories under 2501 grams.[10-12] David and Siegel[12] suggest that this differential holds up even after controlling for differences in gestational age. Thus the higher overall nonwhite neonatal mortality rate in North Carolina in 1980 (13.5 versus 8.1 for whites) was clearly due to lower nonwhite birth weights. The percent of nonwhite births under 2501 grams was 11.9 in 1980, compared with 6.1 percent of white births. For births under 1501 grams, where neonatal mortality is especially high, the nonwhite percent was almost two and one half times the white percent. If nonwhite births in North Carolina had the same weight distribution as white births, nonwhite neonatal mortality would be 6.7 compared with 8.1

Table 2

Changes in Birth-Weight-Specific Neonatal Deaths per 1000 Live Births by Race, North Carolina 1981-1982

	Total				White				Nonwhite			
Birth Weight in Grams	1981 Rate	1982 Rate	% Change	p	1981 Rate	1982 Rate	% Change	p	1981 Rate	1982 Rate	% Change	p
≤ 1000	691.1	687.2	−0.6	.94	723.9	675.4	−6.7	.52	651.3	695.8	6.8	.47
1001-1500	110.1	132.8	20.6	.24	163.5	164.1	0.4	.98	53.5*	101.2	89.2	.03
1501-2000	44.8	33.2	−25.9	.13	55.1	43.1	−21.8	.32	30.2	23.0	−23.8	.45
2001-2500	11.5	14.1	22.6	.29	12.0	13.8	15.0	.60	10.5	14.4	37.1	.28
≥ 2501	1.9	2.1	10.5	.37	1.9	1.8	−5.3	.70	1.8	2.8	55.6	.02
Total	8.8	9.5	8.0	.13	6.9	6.9	0.0	1.00	12.3	14.7	19.5	.02

* This rate is extremely low and probably does not represent the underlying or "true" rate in 1981. The comparable rate in 1980 was 110.7.

Note: The probability (p) values indicate the probability that a change as large as the one observed could have occurred due to random fluctuations in the rates, considering the number of deaths in the numerators. For example, .02 would indicate 2 times out of 100.

for whites, assuming no change in the weight-specific death rates. However, nonwhite postneonatal death rates (i.e., deaths age 28 days to one year) are substantially higher than the white rates for every birth-weight category.

Recent Trends

1976-1980

The contribution of changing birth weights to the decline of North Carolina neonatal mortality from 12.9 in 1976 to 9.8 in 1980 was also examined. Practically none of this reduction can be attributed to increased birth weights. The percent of births under 2501 grams was 8.3 in 1976 and 7.9 in 1980. But the percent of births under 1000 grams actually increased from 0.61 in 1976 to 0.72 in 1980, with most of this increase occurring among nonwhites. Part of this increase could, however, be due to better reporting in 1980 of very low-weight deliveries as live births rather than as fetal deaths.[12] But if we apply the 1976 North Carolina birth-weight distribution to 1980 births and assume the same 1980 weight-specific neonatal death rates, the expected rate of 9.2 is actually lower than the observed rate of 9.8. Therefore, the decline in neonatal mortality from 1976 to 1980 is overwhelmingly due to reductions in weight-specific neonatal death rates. The rates in the under 1001 grams, 1001-1500, 1501-2000, 2001-2500, and greater than 2500 grams birth-weight categories declined by 17, 49, 47, 36 and 24 percent, respectively, over this period. These decreases in the low-weight death rates are associated with steady increases in the percent of low-weight births occurring in Level III (tertiary care) hospitals, where weight-specific death rates decreased from 1976 to 1980. Among births under 1500 grams, the percent occurring in Level III hospitals was 39.6 in 1976 compared with 58.1 in 1980.

1981-1982

The analysis of neonatal mortality into two major components sheds considerable light on the 1982 upturn in infant mortality in North Carolina. Much has been said about the increase in the infant mortality rate from 13.2 in 1981 to 13.7 in 1982, an increase that could be expected to result from random changes nearly 4 times out of 10. Further investigation, however, reveals that *all* of this increase in the infant mortality rate was due to an increase in neonatal mortality, and in fact all of this increase in neonatal mortality was among nonwhites. Neonatal deaths increased from 739 in 1981 to 813 in 1982, or from 8.8 neonatal deaths per 1000 live births to a rate of 9.5 in 1982. The postneonatal death rate declined slightly from 4.4 in 1981 to 4.3 in 1982. Looking at this by race, the white neonatal mortality rate was 6.9 in both 1981 and 1982, while the nonwhite rate increased from 12.3 to 14.7.* We would expect this 20 percent increase in the nonwhite neonatal death rate to occur due to random changes less than 2 times out of 100. Postneonatal deaths per 1000 live births declined by 8 percent for nonwhites, while increasing 3 percent for whites.

The increase in neonatal mortality from 1981 to 1982 was associated with a worsening of the birth-weight distribution. The percent of births less than 2501 grams increased slightly from 7.9 to 8.0, but the number of births under 1000 grams increased by 47 from 586 to 633, or from 0.70 percent of all births to 0.74 percent. This general pattern of change is also apparent for the two racial groups. Yet the increase in the prematurity rate among nonwhites accounts for only a small proportion of the overall increase in the nonwhite neonatal mortality rate. If 1981 nonwhite births are assumed to be distributed by weight like those in 1982 (in percentage terms) and then the actual 1981 weight-specific death rates are applied, an expected nonwhite neonatal mortality rate of 12.5 results. Thus lower birth weights explain only around 8 percent of the 1981-1982 increase in the nonwhite mortality rate from 12.3 to 14.7.

An examination of changes in the weight-specific neonatal death rates from 1981 to 1982 sheds more light on this problem. Table 2 displays these changes. For total births, three of the rates increased and two decreased, though none of these changes was statistically significant at the p = .05 level. For whites also none of the changes was significant. For nonwhites, 4 of the 5 rates increased from 1981 to 1982 and two of these increases were significant at below the .05 level.† These data confirm that the increase in the overall nonwhite neonatal mortality rate was due substantially to increases in weight-specific death rates. These increases in the weight-specific death rates were not associated with a decreasing percent of births in these weight categories occurring in Level III hospitals. Considering also that there were increases in certain race-weight-specific death rates from 1980 to 1981, it appears that the consistent decline of weight-specific neonatal mortality rates that has occurred since at least 1976 has temporarily abated.

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* The race-specific death rates using race at birth from the matched birth/infant death file, which are shown here, may differ slightly from the rates using race as assigned on the death certificate.

† See, however, the first note to table 2.

Discussion

This study demonstrates that examination of "crude" neonatal or infant mortality rates is not sufficient. Birth-weight-specific mortality rates must be examined in relation to the distribution of births by weight. In order to undertake such analysis, matched birth and infant death files are required. Given that the relatively poor ranking of the United States among industrialized nations with regard to neonatal mortality is due largely to low birth weight,[4] it is difficult to justify the unavailability of such data for the entire United States for the direction of national policy.

The results of this analysis have some important implications for North Carolina policies designed to further reduce the neonatal mortality rate. Almost none of the reduction in neonatal mortality since 1976 has been due to increased birth weights. The major improvements in neonatal mortality have resulted from better medical care of small babies in neonatal intensive care units,[1, 10, 13] which has served to reduce the weight-specific neonatal death rates particularly in the 1001 to 2500 grams categories. Williams and Chen[13] suggested that the increased rate of cesarean section for low-weight infants also contributed to the decline of neonatal death rates in California. They found that decreases in birth-weight-specific mortality accounted for 85 percent of the decline of the neonatal mortality rate in the 1970s, with only 15 percent due to improvements in birth weight, and no improvement was observed in the birth-weight distribution for blacks. Goldenberg et al[10] found that only 5 percent of the nearly 50 percent reduction in neonatal mortality in Alabama from 1970 to 1980 could be attributed to changes in birth-weight distributions, and birth-weight changes accounted for 12 percent of the decrease in the white neonatal mortality rate but none of the decrease in the nonwhite rate. David and Siegel[12] found for North Carolina that "better babies," as reflected primarily in increased birth weights but also considering gestational age, accounted for 85 percent of the decline in neonatal mortality from 1968 to 1972, but accounted for only 16 percent of the decline from 1972 to 1977, with the rest of the decline attributable to better weight-specific survival rates or "better care." They also found that improved birth weights and gestational ages were a much less important factor in the decline of neonatal mortality for nonwhites as compared with whites.

It is likely that, in the near future, further major reductions in neonatal mortality will require more than efforts to increase weight-specific neonatal survival after birth, though some improvement may occur by extending neonatal intensive care services to persons who have not had access to them. The birth-weight standardization carried out above suggests that North Carolina weight-specific neonatal death rates are probably already below the United States rates. Goldenberg et al[14] have presented the lowest average weight-specific neonatal mortality rates reported in the medical literature for the 1976-1980 period, and the average 1976-1980 rates for North Carolina were 20 to 65 percent higher than these lowest "literature" rates. By 1981, however, the North Carolina annual rates were below these lowest average 1976-1980 rates for all weight categories except 2001-2500 grams, where they were equal. The trend in weight-specific rates from 1981 to 1982 (table 2) indicates that future large increases in neonatal survival rates will be difficult to attain. If we apply the 1979 Swedish birth-weight distribution to 1979 North Carolina births and assume that 1979 North Carolina weight-specific neonatal death rates would be in operation, the expected rate is 5.6 compared with 5.0 in Sweden and compared with an actual North Carolina 1979 rate of 10.4. North Carolina weight-specific neonatal death rates therefore appear to be very close to those in Sweden, which has one of the lowest crude neonatal death rates in the world.

Thus, further large reductions in neonatal mortality in North Carolina are not likely to result from neonatal intensive care and other methods that increase the rate of survival after birth, though certainly some improvements can be made in this area by extending these services to groups that have not had access to them in the past. If North Carolina is to reduce neonatal mortality to the United States average or lower, we must adopt policies that will lead to a substantial reduction in low-weight births.

The results above also show that the North Carolina racial gap in neonatal mortality could be eliminated and in fact reversed if North Carolina nonwhites achieved the birth-weight distribution of whites, with no change in neonatal survival rates. Several of the studies cited above indicate that improved birth weights have been a much less important factor in the decline of nonwhite neonatal mortality compared with whites, including the study by David and Siegel[12] for North Carolina during the 1968 to 1977 period. Goldenberg et al[10] found for Alabama that shifts in birth-weight distributions for nonwhites from 1970 to 1980 would have *increased* the neonatal mortality rate if weight-specific death rates had not been declining at the same time.

The data in the present study show a widening racial gap in neonatal mortality: the nonwhite crude neonatal mortality rate was 35 percent higher than the white rate in 1976, 67 percent higher in 1980, 77 percent higher in 1981, and 113 percent higher in 1982. The percent of nonwhite births under 2501 grams remained almost exactly twice the white percent during this 1976-1982 period (12.1 versus 6.1 in 1982), but the percent of births under 1001 grams for nonwhites changed from 2.3 to 2.9 times the white percent. Death rates in this very low weight category have not declined as rapidly as those in the 1001-2500 grams categories. The ratio of nonwhite to white neonatal death rates at each weight category did not change substantially from 1976 to 1980. From 1981 to 1982, the weight-specific death rates for nonwhites worsened considerably in comparison with the white rates, contributing to the widening racial gap (table 2). In fact, the nonwhite neonatal death rate was higher than the white rate in 1982 for three of the birth-weight categories, whereas in 1980 and 1981 all of the weight-specific nonwhite rates had been lower. The worsening of these nonwhite rates from 1981 to 1982 in comparison with the white rates was not associated with a relatively lower percent of nonwhite births in these weight categories occurring in Level III hospitals.

These recent increases in nonwhite weight-specific neonatal death rates are cause for concern, particularly the increase in the over-2500-grams category (table 2). But there is still a critical need to reduce the high rate of low-weight births among nonwhites in North Carolina, and much room for improvement. "The intensive care approach alone will not suffice to close the racial gap in newborn mortality."[12] Williams and Chen[13] suggest that the most obvious target for sustaining the decrease in neonatal mortality rates is the reduction of low-weight births among blacks, and the data in the present study support this conclusion. Prenatal medical care strategies alone are not likely to solve this problem, since the weight distribution of live births in any population is closely linked to aspects of social class.[4] Low birth weight is strongly associated with low socioeconomic status.[5]

The application of neonatal intensive care technology has led to very rapid increases in neonatal survival rates, but strategies to increase birth weights may not show such rapid results. A number of interventions have been underway in North Carolina and are increasing, such as provision of prenatal care, nutritional supplementation and counseling, and health education. The overall low-birth-weight rate did decline from 8.3 percent in 1976 to 7.9 percent in 1981, and certainly efforts of this type must be continued. In addition, new medical care strategies such as early detection of incipient premature labor and treatment with tocolytic agents have shown some promise.[15] A large and sustained reduction of low-weight births is, however, also dependent upon the longer-term process of overall socioeconomic development and associated factors such as better education, employment opportunities, and incomes. Though these changes may be difficult to implement, they are nevertheless very important. Further improvements in neonatal mortality through postnatal medical interventions are not only limited, they are also very costly. Prevention of low-weight births will reduce not only the overall neonatal mortality rate but also neonatal intensive care costs. Sweden, which has about the same number of deliveries per year as North Carolina, has only about half as many low-weight births and neonatal deaths, and about half the number of ventilator-equipped neonatal intensive care beds as North Carolina.[12]

While the outcome measure in this study was neonatal mortality, another result of increasing birth weights would be the reduction of neonatal morbidity. Low-weight babies are at higher risk for intracranial hemorrhage and birth asphyxia.[12] Without losing sight of the positive contribution of intensive perinatal medical care in reducing morbidity,[16] "a strategy aimed at reducing the prematurity rate should be more effective in reducing morbidity in the population than a strategy focused primarily on helping premature babies survive, once factors have combined to cause a premature birth."[12]

In summary, this study has shown that North Carolina's higher neonatal mortality is due entirely to lower birth weights, when compared with the United States, and that little improvement in birth-weight distribution has occurred since at least 1976. Further, from 1981 to 1982 the percent of low-weight births actually increased. Clearly, a major part of our agenda for preventing future neonatal deaths in North Carolina should be the implementation of programs that reduce the number of low-birth-weight babies. Given the impact of low birth weight on morbidity and health care costs as well as on neonatal mortality, perhaps the low-birth-weight rate should become the major performance measure for maternal and child health programs.

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PHYSICIANS' FORUM

Women Doctors

Eugene W. Linfors, M.D., editor

The question for the July issue of the Journal is: **Will the increase in number of women doctors change the practice of medicine? What effect will more women doctors have on the penetration of the market by Health Maintenance Organizations?**

From Janice E. Daugherty, M.D., a family practitioner in Greenville

I think more women in medicine will improve medical care in general, but especially care for women. The more familiar a physician is with the patient's situation, the better care he or she can provide to that patient. Since the cultural milieu may be vastly different for men and women (even of similar socioeconomic and geographic origin), decreasing the "cross-cultural" nature of the health care experience can lead to improved quality of medical service. A truly sympathetic caregiver can do much to improve the patient's self-confidence in handling symptoms or disease, as well as providing guidance for life-stage situations, which often has personal experience behind it. For example, the best caregiver for a nursing mother is a physician who herself has *successfully* breastfed — especially through the trials and tribulations of nursing while employed full-time. The ability to convey the attitude that "you can do it, it won't necessarily be easy, but I'm here to help if you develop a problem you can't handle alone" will do much to erase the sometimes pathologically dependent role women have been forced into through the past use of antianxiety agents and pain pills.

Moreover, since a majority of physician visits are made by women, improving that interaction can significantly raise the overall quality of health care.

Increasing numbers of women allow changes in the way medicine itself is practiced. By seeking alternatives to the "24 hour-a-day doctor" role — necessitated by a desire to maintain a home and family as well as a medical practice — women in increasing numbers will humanize the medical profession. The need to communicate to patients that "Yes, I care about you, but I care about myself and my family also. I will be available for your needs when I can; when I cannot be available you will be cared for by a colleague whom I trust" often leads to women physicians seeking more structured practice in groups, HMOs, salaried positions, etc. Working fewer hours usually means making fewer dollars; balancing this somewhat is the fact that a majority of women physicians are in families for which she is not the sole breadwinner.

Improved lifestyle and family relationships not only affect women physicians; male physicians also benefit from the trend that allows them some freedom from "medicine as a jealous mistress." Male physicians traditionally may have hesitated to challenge the norms of medical practice; women physicians do it out of necessity.

In summary then, I see change brought about by increased numbers of women physicians as coming in three major areas: improved quality of medical care principally to women, more humane physician lifestyle with fewer total hours of practice, and lowered average physician income.

From Daniel L. Dolan, M.D., an internist in Asheville

When I hear this matter discussed in open forum, it invariably provokes heated discussion and feelings. Your query has therefore prompted me to attempt to locate some objective data, which I am happy to enclose.

Our AHEC Residency Program in Asheville is in Family Medicine, traditionally taking eight residents at each level for a three-year period. We have recently reduced to six in partial response to the perceived physician excess. I have reviewed the careers of all those in our program (which opened its doors in 1975). Our first graduating class was in 1978.

These data should not be extrapolated to other subspecialty areas since they represent only one small sample in one local Family Practice Residency Program. Traditional subspecialties attracting women physicians (such as obstetrics, pediatrics, etc.) might show different data. Nonetheless, here is an objective sampling which, in its overall, suggests that women tend to seek more part-time employment than a full-time private practice, and are less inclined to establish longitudinal on-going patient responsibilities than their male counterparts.

Dr. E. Grey Diamond has recently pointed out that women physicians, in order to have a full medical career, must have a different set of support systems at home. The spouse must take over many home responsibilities with or without hired housekeepers (E. Grey Dimond: "Women in Medicine" — Two Points of View. JAMA 1983; 249:207-210). Of interest is the fact that one of our three women physician graduates in full-time private practice exactly fits this model. She is a physician and her husband is a registered nurse who participates in a major way in the care of their two young children and the home (although he also works in a nursing role). This unusual situation is quite successful for them and proves that when such arrangements are possible, the Dimond model can be quite successful.

	Full-time private practice	Part-time employment and emergency room work	Full-time non private practice (institutional, public health, etc.)	Voluntary drop-out	Dismissed from program	Died
MALE (N=36)	25 (69%)	2 (5.5%)	4 (11.5%)	2 (5.5%)	2 (5.5%)	1 (3%)
FEMALE (N=13)	3 (23%)	3 (23%)	2 (15%)	4 (31%)	1 (8%)	0 (0%)

Lastly, I could only speculate as to the impact of women physicians on HMOs, PPAs and similar economic "market force" arrangements. From the above data, it would be reasonable to project that where large group practice arrangements are possible within these economic units, women physicians would likely be attracted to them where coverage would be liberally provided. Even where these economic units extend to many different types of practice as a loose financial federation without practice cross-coverage, I would think women's participation would be likely as an added source of income. Male physicians would be more traditionalist oriented toward private fee for service practice as long as it was financially feasible. If Minneapolis is any example, all will ultimately accede to similar arrangements if their community medical structure goes in this direction. I am not convinced that patients will benefit from these arrangements.

I do not claim erudition in the above remarks. If women physicians are less inclined to occupy full-time equivalents, the perceived over-production of physicians may be significantly lessened and future medical manpower planning should take this into consideration.

From Claude A. Frazier, M.D., an allergist in Asheville

I, personally, don't believe the increase in women physicians will make any fundamental change in the practice of medicine, unless of course, women physicians flock to a particular discipline, such as gynecology, obstetrics or pediatrics. Even then, the presence of women physicians has provided women patients, who often prefer a specialist of the same sex in these fields, a choice.

The same can be said for the penetration of women physicians into the Health Maintenance Organizations and for the dramatic increase of women in the work force these last few decades increasing the number of women cared for under Health Maintenance Organization contracts. Again the presence of women physicians offers choice, a choice no doubt greatly appreciated by women patients.

All in all, I strongly believe the increase of women physicians has had a great and good impact on medicine in general.

From Jack Hughes, M.D., a urologist in Durham

The increase in the number of women doctors will likely change the practice of medicine in at least two ways.

The first effect will be part of that total increase in the supply (or over-supply) of doctors both men and women. For example, the "over-supply" will lead to increasing competition for patients which undoubtedly will make physicians' services more readily available in the evenings and on weekends. There will be more time to spend with each patient, fewer working hours, lower incomes, etc. Health care costs will not be lowered but the rate of increase undoubtedly will be slowed.

Secondly, the practice of medicine will change to the degree that women physicians sacrifice income for regular hours, more free time to rear children, be a part-time housewife, or just enjoy time off. Such women physicians may be willing to work in salaried positions for smaller hourly incomes. HMOs, PPOs and similar groups will probably be in a better position to offer this type of employment than would traditionally structured practices and thereby be more competitive in the health care market.

But then of course most of the women physicians may become like the typical men physicians of the past and work longer hours and with even greater intensity to prove some point or for whatever reason. In which case my second point will be moot.

From Richard Janeway, M.D., Vice President for Health Affairs in Winston-Salem

Whenever I am asked what the effect of increasing numbers of women in medicine will be, I am tempted to say, "It's got to be better." That reply, although trite enough for the question, of course, is not true. In a recent survey conducted by Dr. George Rhinehart, Associate Professor of Sociology at the University of Alabama under the auspices of the National Opinion Research Center, physicians were rated second only to Supreme Court Justices as the most prestigious profession. We achieved a rating of 93 on a scale of 20-100. In 1963 and 1947, when similar surveys were compiled, physicians led the list with an identical 93 rating. Whatever else can be said about our predominantly male predecessors and compatriots, they apparently have in the main conducted themselves with honor and professionalism. I wonder, however, if that is so much a reflection of their maleness as the caliber of person that has historically been drawn to the healing art?

Will the increase in the number of women doctors change the practice of medicine? My answer to this question is a resounding yes, but no. The yes results from the biologic and cultural imperatives that affect women physicians. Let me explain.

Few young adults, if they are honest with themselves, can deny that they have considered having children. For women, this involves the necessity, aside from the rare occasions of adoption, of bearing the child. In addition, despite tremendous advances made by males in recent years

— one is even tempted to say "we've come a long way baby" — the cultural reality of 1984 is that there are still relatively few truly emancipated female or male spouses. This means that most of the time, the working woman and mother also has primary responsibility for the household. The combination of these biologic and cultural factors has, I believe, affected women's choices of medical specialties in the past. Disciplines such as surgery, that involve long hours of standing, have been seen as incompatible with pregnancy. Specialties with unpredictable hours such as obstetrics or transplantation have been avoided because of their potential impact on family responsibilities. Only multi-member private practice situations have been sought because maternity absences impact one, two or three member partnerships too drastically. Contrarily, specialties such as pathology, radiology or dermatology have been traditional favorites with women in medicine, because of the more structured nature of the practice.

In 1984 the imperatives remain, but the women have changed. So have the times. First, we are in the midst of a renaissance for young women in this country. Effective birth control which women can control has enabled women to be as sexually active as they wish without fear of an unplanned pregnancy. The women's liberation movement has shown, even forced women to consider any profession their domain. Wonder women such as Tenley Albright have shown that it is possible to win an Olympic gold medal, raise a family, and be a surgeon in the same lifetime. In short, the young women in America today have been taught that they can have it all: and now they want it. They do not believe old mores such as "nice girls are not aggressive enough to be general surgeons or deans." Today's college graduates, the women I interview for medical school, have no such reservations. They know they can find a way to do both and more. Today's woman professional is going to insist that her biologic imperative be accommodated, not delayed or denied.

Second, there are several trends in medical practice that should be attractive to young physicians of both sexes trying to combine career and family. Health maintenance organizations, prepaid practice organizations, operations such as MedFirst, and even emergency medicine positions all have the advantage of predictable hours, no call-commitment, and no dedicated patient population that must be covered during off-hours. I believe such positions will be increasingly popular with our junior peers. For women in particular, these new options will have the effect of making more specialties feasible and appealing.

Aside from the changes brought about by the biologic and cultural imperatives described above, however, it is my contention that increasing numbers of women will not change greatly the essence of American medicine, as long as our women are selected as carefully as our men. Inevitably, sheer numbers of women entering the field will result in enough experienced teachers, scientists, and leaders to impact medicine's power structure, but that is in the future. It is probably risky for all concerned to accelerate the maturation process too greatly.

I doubt the basis for the contention that increasing the numbers of women physicians will provide an added measure of tenderness and compassion to the profession. Tenderness and compassion are not exclusively qualities of women.

I reject the contention that the increasing number of women in medicine will result in loss of prestige for the profession. If, as I have heard, medicine enjoys less regard as a profession in places such as Russia where women physicians predominate, then I ask, "Which came first?" It is well to remember that until about 20 years ago really choice jobs were rarely available to women. Considering this, it seems more likely to me that the predominance of women physicians in some countries reflects the fact that the field of medicine is not generically attractive to the male. In this country, we do not have such a situation. Rather, we have a long tradition during which physicians have been among the most respected members of society. It is hard to see how anything short of widespread vice, corruption and arrogance within the profession could jeopardize this enviable position.

I look with optimism to the time when women in medicine are no longer tokens, but part, even leaders of the team. I hope that increasing the numbers of women physicians will result in natural corrections of many of the frustrations which women physicians endure today: inadequate call accommodations, lounge space and locker facilities; inequitable pay; and truncated opportunities for advancement. I see nothing to fear from more women in American medicine. It is perfectly clear to me that maleness is not the quality we need to worry about losing. Rather, we should strive to retain that undefinable and indescribable combination of inquiring mind, depth of character and sensitive heart that has made us 93, 93 and 93.

From Josephine E. Newell, M.D., Medical Director of North Carolina Health Benefit Plan

Women physicians face exactly the same problems as do male physicians. We are told that today's medical graduates will face tremendous financial obligations representing educational expenses as well as medical practice "start-up" expenses. This burden will be no easier for females than for males. Many of these young graduates will already have marital responsibilities and children before they enter practice. Certainly, these responsibilities will weigh more heavily on married women physicians than on the majority of their male counterparts. The promise of regular working hours in an HMO set-up would necessarily be tempting to any parent with minor children in the home.

Unfortunately, many North Carolina physicians who favor private practice have closed their eyes to "penetration of the market" by Health Maintenance Organizations. While these physicians have been asleep at the switch, North Carolina's medical world has already been penetrated by three giant corporations — each with an HMO model. North Carolina Blue Cross/Blue Shield assures us that they are being successful in selling their HMO model. HealthAmerica Corporation of North Carolina has run full page ads in all major North Carolina newspapers for the past two months, and states that they are having little difficulty in contracting with both physicians and "business." Now, we are told that the largest and most successful HMO in the nation, Kaiser Permanente, will be established in the Research Triangle by July 1, 1984. Since there has, as yet, been no great influx of women physicians in North Carolina, one must assume that there are other factors which led these large corporations to select North Carolina as their marketplace. Their corporate interests are similar to those of other large corporations already located in the Research Triangle. The obvious answer is the rich marketplace for HMOs, provided by the work forces of those other corporations.

In its great wisdom, the Federal Government has created a surplus of physicians — both male and female. Many of these young physicians will find a diminishing market for private practice in their chosen locale, because of the penetration of HMOs and proprietary hospitals with salaried physicians comprising the medical staff. Faced with large debts and families already in place, these young physicians may find guaranteed income and fewer working hours to be extremely attractive — both to men and women.

The anticipated increase in women physicians will not change the practice of medicine. That change will be brought about by the marketplace, political influence, proprietary medicine and entrepreneurial individuals who are not primarily concerned with the quality of medical care provided.

In summary, the women physicians with whom I have been associated during the past thirty years have all been good physicians, who render the highest possible quality of medical care. Most of them have gone the extra mile to shoulder more than their share of the load, despite certain inequities which were to be expected in a predominantly male profession. However, women physicians must not be blamed for the inevitable change in the practice of medicine in North Carolina or the penetration of the market by Health Maintenance Organizations. The new generation of male and female physicians will set the course of medical practice for future years.

From Robert L. Phillips, M.D., a neurosurgeon in Greensboro

Those who are misled into believing Shakespeare's generalization in the *Tempest* — "What's past is prologue," will surely believe that medicine will suffer if the number of women going into this profession continues to escalate. "Their track record is poor . . . they occupy a seat in medical school (that a man should have!), go into practice a few years, then many have a family and kiss medicine good-bye . . . what a waste!" There are still a lot of these "hey-hey" boys around who also believe women have not demonstrated "staying power" and are convinced that only the feminine misfits seek medicine as a career. They freely admit that "occasionally an exceptional one comes along but look at the waste in just getting *that one*." "These women will lead us straight to socialized medicine for it suits their way of life . . . 9 to 5." To our perpetual prophets of doom, all I can say is "gentlemen, change your database!" You can't take a splinter out of someone else's eye if you have a two-by-four in yours. Change is upon us . . . contract medicine is knocking at your door and by the way, women in medicine *will* flourish. With due respect to Shakespeare, not much in the past will help us through this period.

Medicine is, among other things, a social institution. Fortunately, we no longer speak of medical care but instead, health care. This includes help from many people . . . the physician being one part of this complex effort. Those who have felt threatened have used Archie Bunker's technique in trying to "stifle" input from other allied health professionals but fortunately to no avail. What a waste of time and effort, on both sides, when clearly, the tide for comprehensive health care has been in for a long time. The minority struggle has indeed had its casualties, but the Chinese "dripping water" technique has prevailed. Medicine *needs*, as any other social organization does, the input from our women. Many of us have seen organizations change dramatically for the good when women entered the decision making process. They can be innovative, aggressive and often add a new dimension. Think a minute about our male dominated AMA. It has *opposed* almost everything and *proposed* very little . . . the latter usually being a knee-jerk reaction. The HMOs and all the other alphabetical changes are here by necessity. Would it have been different if our medical hierarchy had had feminine input?

Many of us believe women generally are tougher, have more patience, more durability and, perhaps because of the above, have more empathy than their male counterparts. These qualities can only help our health care system. Obviously, some will have the same frailties that the rest of us have and just because one is a female physician, doesn't necessarily mean she will be another Taussig, Morrow or Sharpless . . . but it is my opinion that medicine will continue to be enhanced by her presence. It is long overdue. Conceptually, the women already in medicine and those coming in will probably adapt as well as, if not better than, the men to the HMO since they have been truly the minority group in the social transformation.

Finally, I fully believe that she will, as any good physician will, look beyond the immediate and obvious appearance of things; will cultivate breadth of vision as well as depth of learning; will explore the philosphic and social dimensions of medicine as well as the scientific; and will practice her profession not only with knowledge, judgment and skill, but also with faith, wisdom and love.

From Rose Pully, M.D., a family practitioner in Kinston

In reply to the first question, "Will the increase in number of women doctors change the practice of medicine," my spontaneous remark is: "I certainly hope so for the continuing improvement of the practice of medicine." Yet why would it be expected to change? Are we looking at the female physician to fulfill a role attributed to her because of her gender? Is it true that attributes of nurturing, compassion, people orientation and sensitivity are found solely in women? Of course not. These qualities also reside in the male physician but are downplayed. Despite qualities traditionally attributed to women, the characteristics women display as physicians are formulated by the impact of their professional education, by their adaptation of medical roles and by the organization of their professional life. Women physicians more nearly resemble men physicians in professional attributes than they do other women in the population (Eisenberg: Women as Physicians. J Med

Ed 1983;58:534-541). Women physicians in my early career considered it a compliment to be told "you think like a man professionally." You can imagine the repercussions of such a "compliment" today.

It is of interest that medical schools today are emphasizing the "humanistic attitude or approach in caring for the patient." Even the surgeons are asking for social histories. Since this lack of "caring" on the part of the physician has been a major criticism of the profession and yet, generally, caring is innate in every young medical student, this trait should be constantly nurtured throughout the student and residency years. Thus it may be in full bloom for the years to come.

To look at the past as a measure for the future it is true that women physicians and some of their formal organizations have been more conscious of social issues and a great deal of their energies have been spent in patient caring issues, parent-child interests, and clinics in deprived areas of the world from China to Appalachia. Women physicians have either been happier or accepting of their role in primary care fields, ambulatory and preventive medicine than their male counterparts. Maybe this is accepting realism and adaptation to their life styles. These roles no doubt will be continued by the increasing number of women doctors. Without addressing the biological gender difference specifically it is true that gaps in training and in the ultimate practice of her profession affords the woman with husband and young children some management and psychological problems. This however usually changes the practice of medicine only in the timing sequence. Despite high promise of the increase in male caring responsibilities in home and family and the actual occurrence of this rare happening, I believe that overall acceptance of this idea may be slow in development.

In the past women have largely chosen specialties of pediatrics, psychiatry, general medicine and obstetrics. However with more women physicians their ranks are expected to increase in the surgical subspecialties. With the comfort of their role as medical students in both competitive and non-competitive activities the young female physicians will be more assertive and professionally ambitious than the average physician of thirty years past. How this may change the practice of medicine is uncertain but it should change the system from which the practice originates.

Any exceptional traits to improve patient-physician relationships or change the practice of medicine that are attributed to women physicians need to be discovered and accentuated for both sexes of the medical profession.

In response to the question, "what effect will more women doctors have on the penetration of the market by Health Maintenance Organizations," I have had less experience to reply. As I understand it, the HMO system is a more structured system with regularly scheduled hours, less night call demands than solo practice and some incentives for reduced costs of health care.

In a study by Rosen, Heims, Martindale (Practice plans of today's medical students. J Med Ed 1981;56:57-59) of practice plans of today's medical students the findings indicated that

1. students do not plan to work as hard as predecessors.
2. the future physicians may not have same degree of productivity as is measured today.
3. group practice was planned by 55% of the women and by 48% of the men.
4. gender roles showed no significant difference in their attitudes in practice planning.

All of these have implications for health manpower planning. With the above figures and findings as indicators it could be assumed that the increase in the total number of physicians rather than female physicians would have some effect on the penetration of the market by HMOs. However it cannot be overlooked that the rising cost of health care is an incentive for perpetuation of this system of delivery of health care rather than increasing ranks of women physicians.

From Margaret C. Swanton, M.D., a pathologist in Clinton

While I was pleased to be asked to participate in your forum related to women physicians, I really have no data to use for a comment. I am a hospital-based physician who has always (30+ years) been on a full-time basis just like my male colleagues. I have no idea how young women physicians are altering the traditional format of practice involving direct patient care. The only one in my community has no choice but private practice, altered since the birth of her baby only by decreased admissions of hospital patients under her care.

From Eldora H. Terrell, M.D., an internist in High Point

It seems unlikely that women doctors who remain single will change the practice of medicine in any significant way. On the other hand, women who choose to combine marriage and children with a medical career soon learn that they cannot serve two masters. They cannot simultaneously be full time mother and full time physician. Their choices are difficult and involve sacrifices. These women doctors can be expected to gravitate toward employment opportunities which offer regular hours and little or no responsibility away from the job. Private practice of medicine does not fit that description. This may not be ideal in terms of career goals but it will be an acceptable compromise. As women have in the past, these will work for less pay in exchange for flexibility of schedule or limitation of hours. Health Maintenance Organizations and other alternatives to private practice can be expected to eagerly tap this rapidly increasing resource of less expensive medical care-givers. This will contribute to their growth and success and to the decline of private practice as we have known it.

- EDITOR'S NOTE: It sounds like women can have whatever impact on medicine that they choose. Decisions women physicians make regarding their time will need to be considered by health man (and woman) power planners and those concerned by the doctor glut.

"I WOULDN'T TREAT MY BIKE THE WAY YOU TREAT YOUR BODY."
—Judy Lafferty

When Judy Lafferty prepares for a race, she checks every part of her bike.

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We need your money to help us win this race.

SHARE THE COST OF LIVING.

GIVE TO THE AMERICAN CANCER SOCIETY.

This space contributed as a public service

References
1. Stone PH Turi ZG Muller JE Efficacy of nifedipine therapy for refractory angina pectoris *Am Heart J* 104 672-681 September 1982
2. Antman E, Muller J, Goldberg S et al Nifedipine therapy for coronary-artery spasm Experience in 127 patients *N Engl J Med* 302 1269 1273, June 5, 1980

BRIEF SUMMARY
PROCARDIA® (nifedipine) **CAPSULES** For Oral Use

INDICATIONS AND USAGE I Vasospastic Angina PROCARDIA (nifedipine) is indicated for the management of vasospastic angina confirmed by any of the following criteria 1) classical pattern of angina at rest accompanied by ST segment elevation 2) angina or coronary artery spasm provoked by ergonovine or 3) angiographically demonstrated coronary artery spasm In those patients who have had angiography the presence of significant fixed obstructive disease is not incompatible with the diagnosis of vasospastic angina provided that the above criteria are satisfied PROCARDIA may also be used where the clinical presentation suggests a possible vasospastic component but where vasospasm has not been confirmed e g where pain has a variable threshold on exertion or in unstable angina where electrocardiographic findings are compatible with intermittent vasospasm or when angina is refractory to nitrates and or adequate doses of beta blockers

II. Chronic Stable Angina (Classical Effort-Associated Angina) PROCARDIA is indicated for the management of chronic stable angina (effort-associated angina) without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and or organic nitrates or who cannot tolerate those agents

In chronic stable angina (effort associated angina) PROCARDIA has been effective in controlled trials of up to eight weeks duration in reducing angina frequency and increasing exercise tolerance but confirmation of sustained effectiveness and evaluation of long-term safety in those patients are incomplete

Controlled studies in small numbers of patients suggest concomitant use of PROCARDIA and beta blocking agents may be beneficial in patients with chronic stable angina but available information is not sufficient to predict with confidence the effects of concurrent treatment especially in patients with compromised left ventricular function or cardiac conduction abnormalities When introducing such concomitant therapy care must be taken to monitor blood pressure closely since severe hypotension can occur from the combined effects of the drugs (See Warnings)

CONTRAINDICATIONS Known hypersensitivity reaction to PROCARDIA

WARNINGS. Excessive Hypotension Although in most patients the hypotensive effect of PROCARDIA is modest and well tolerated occasional patients have had excessive and poorly tolerated hypotension These responses have usually occurred during initial titration or at the time of subsequent upward dosage adjustment and may be more likely in patients on concomitant beta blockers

Severe hypotension and or increased fluid volume requirements have been reported in patients receiving PROCARDIA together with a beta blocking agent who underwent coronary artery bypass surgery using high dose fentanyl anesthesia The interaction with high dose fentanyl appears to be due to the combination of PROCARDIA and a beta blocker but the possibility that it may occur with PROCARDIA alone with low doses of fentanyl in other surgical procedures or with other narcotic analgesics cannot be ruled out In PROCARDIA treated patients where surgery using high dose fentanyl anesthesia is contemplated the physician should be aware of these potential problems and if the patient s condition permits sufficient time (at least 36 hours) should be allowed for PROCARDIA to be washed out of the body prior to surgery

Increased Angina Occasional patients have developed well documented increased frequency duration or severity of angina on starting PROCARDIA or at the time of dosage increases The mechanism of this response is not established but could result from decreased coronary perfusion associated with decreased diastolic pressure with increased heart rate or from increased demand resulting from increased heart rate alone

Beta Blocker Withdrawal Patients recently withdrawn from beta blockers may develop a withdrawal syndrome with increased angina probably related to increased sensitivity to catecholamines Initiation of PROCARDIA treatment will not prevent this occurrence and might be expected to exacerbate it by provoking reflex catecholamine release There have been occasional reports of increased angina in a setting of beta blocker withdrawal and PROCARDIA initiation It is important to taper beta blockers if possible rather than stopping them abruptly before beginning PROCARDIA

Congestive Heart Failure. Rarely patients usually receiving a beta blocker have developed heart failure after beginning PROCARDIA Patients with tight aortic stenosis may be at greater risk for such an event

PRECAUTIONS General: Hypotension Because PROCARDIA decreases peripheral vascular resistance careful monitoring of blood pressure during the initial administration and titration of PROCARDIA is suggested Close observation is especially recommended for patients already taking medications that are known to lower blood pressure (See Warnings)

Peripheral edema: Mild to moderate peripheral edema typically associated with arterial vasodilation and not due to left ventricular dysfunction occurs in about one in ten patients treated with PROCARDIA This edema occurs primarily in the lower extremities and usually responds to diuretic therapy With patients whose angina is complicated by congestive heart failure care should be taken to differentiate this peripheral edema from the effects of increasing left ventricular dysfunction

Drug interactions Beta-adrenergic blocking agents (See Indications and Warnings) Experience in over 1400 patients in a non-comparative clinical trial has shown that concomitant administration of PROCARDIA and beta-blocking agents is usually well tolerated but there have been occasional literature reports suggesting that the combination may increase the likelihood of congestive heart failure severe hypotension or exacerbation of angina

Long acting nitrates PROCARDIA may be safely co-administered with nitrates but there have been no controlled studies to evaluate the antianginal effectiveness of this combination

Digitalis Administration of PROCARDIA with digoxin increased digoxin levels in nine of twelve normal volunteers The average increase was 45% Another investigator found no increase in digoxin levels in thirteen patients with coronary artery disease In an uncontrolled study of over two hundred patients with congestive heart failure during which digoxin blood levels were not measured digitalis toxicity was not observed Since there have been isolated reports of patients with elevated digoxin levels it is recommended that digoxin levels be monitored when initiating adjusting and discontinuing PROCARDIA to avoid possible over- or under-digitalization

Carcinogenesis mutagenesis impairment of fertility When given to rats prior to mating nifedipine caused reduced fertility at a dose approximately 30 times the maximum recommended human dose

Pregnancy Category C Please see full prescribing information with reference to teratogenicity in rats embryotoxicity in rats mice and rabbits and abnormalities in monkeys

ADVERSE REACTIONS The most common adverse events include dizziness or light-headedness peripheral edema nausea weakness headache and flushing each occurring in about 10% of patients transient hypotension in about 5% palpitation in about 2% and syncope in about 0 5% Syncopal episodes did not recur with reduction in the dose of PROCARDIA or concomitant antianginal medication Additionally the following have been reported muscle cramps nervousness dyspnea nasal and chest congestion diarrhea constipation inflammation joint stiffness, shakiness sleep disturbances blurred vision difficulties in balance dermatitis pruritus urticaria fever sweating chills and sexual difficulties Very rarely introduction of PROCARDIA therapy was associated with an increase in anginal pain possibly due to associated hypotension

In addition more serious adverse events were observed not readily distinguishable from the natural history of the disease in these patients It remains possible however that some or many of these events were drug related Myocardial infarction occurred in about 4% of patients and congestive heart failure or pulmonary edema in about 2% Ventricular arrhythmias or conduction disturbances each occurred in fewer than 0 5% of patients

Laboratory Tests Rare mild to moderate transient elevations of enzymes such as alkaline phosphatase CPK LDH SGOT and SGPT have been noted and a single incident of significantly elevated transaminases and alkaline phosphatase was seen in a patient with a history of gall bladder disease after about eleven months of nifedipine therapy The relationship to PROCARDIA therapy is uncertain These laboratory abnormalities have rarely been associated with clinical symptoms Cholestasis possibly due to PROCARDIA therapy has been reported twice in the extensive world literature

HOW SUPPLIED: Each orange soft gelatin PROCARDIA CAPSULE contains 10 mg of nifedipine PROCARDIA CAPSULES are supplied in bottles of 100 (NDC 0069-2600-66) 300 (NDC 0069 2600-72) and unit dose (10x10) (NDC 0069-2600-41) The capsules should be protected from light and moisture and stored at controlled room temperature 59 to 77 F (15 to 25 C) in the manufacturer s original container

More detailed professional information available on request

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Quotes from an unsolicited letter received by Pfizer from an angina patient.
While this patient's experience is representative of many unsolicited comments received, not all patients will respond to Procardia nor will they all respond to the same degree.

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"My daily routine consisted of sitting in my chair trying to stay alive."

"My doctor switched me to PROCARDIA[*] *as soon as it became available. The change in my condition is remarkable."*

"I shop, cook and can plant flowers again."

"I have been able to do volunteer work...and feel needed and useful once again."

PROCARDIA can mean the return to a more normal life for your patients—having fewer anginal attacks,[1] taking fewer nitroglycerin tablets,[2] doing more, and being more productive once again.

Side effects are usually mild (most frequently reported are dizziness or lightheadedness, peripheral edema, nausea, weakness, headache and flushing, each occurring in about 10% of patients, transient hypotension in about 5%, palpitation in about 2% and syncope in about 0.5%).

for the varied faces of angina

PROCARDIA®
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*Procardia is indicated for the management of:
1) Confirmed vasospastic angina.
2) Angina where the clinical presentation suggests a possible vasospastic component.
3) Chronic stable angina without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and/or nitrates or who cannot tolerate these agents. In chronic stable angina (effort-associated angina) PROCARDIA has been effective in controlled trials of up to eight weeks' duration in reducing angina frequency and increasing exercise tolerance, but confirmation of sustained effectiveness and evaluation of long-term safety in these patients are incomplete.

Please see PROCARDIA *brief summary on adjoining page*

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North Carolina Medical Journal

Features for Patients July 1984

GENETIC DISEASES

Henry N. Kirkman, M.D.

To understand disorders affecting the human population, American physicians and medical students during the first half of this century had to spend long hours learning about diseases caused by bacteria and, later, about viruses. The need for understanding the infectious diseases remains as strong as ever. Relaxation of our efforts in immunizing children, for example, could bring a return of epidemics of paralysis from poliomyelitis or of brain damage from whooping cough. To understand diseases affecting the human population during the latter half of this century, however, physicians and medical students are having to learn also about another group of disorders — the genetic or hereditary diseases. Genetic disorders are the reason for hospitalization of about one fourth of the infants and children who are in the larger municipal and teaching hospitals of North America. Some of these children have conditions that are purely genetic. Examples are muscular dystrophy and hemophilia. Others have conditions that are partly genetic, such as cleft palate and spina bifida. The present situation is very different from conditions 50 years ago, when genetic disorders accounted for only a small percentage of hospitalized infants and children. Does this recent trend mean that atomic bomb testing and industrial pollution have brought new genetic problems to the human population? Almost certainly not. This trend, instead, has occurred because some infectious diseases such as tuberculosis, typhoid fever, and diphtheria no longer account for a large proportion of hospitalized patients. In addition, certain conditions are now recognized as being genetic, or partly genetic, whereas their genetic nature was not recognized in earlier decades.

Genetic diseases have importance because they account for a higher proportion of illnesses than before. They also have importance because they can be understood, anticipated, prevented and treated more readily than before. We still cannot always tell parents why their infant has a birth defect, but many times the parents can be given a general explanation of how the defect occurred and an estimate of the chances that a future child will be similarly affected. Since we have begun to understand the nature of genetic diseases only relatively recently, we should not be surprised to realize that popular misconceptions exist about genetic diseases. Some of those misconceptions are listed in the accompanying table.

Table 1.

Common Misconceptions about Genetic Diseases

1. This is the first child in our family to have this condition. Therefore, the condition is not likely to affect future children.
2. The parents of that child must come from bad genetic stock.
3. My friend, Mrs. X, has an uncle with similar symptoms. Therefore, this condition in our family must be the same, and inherited the same, as his.
4. We do not plan to have further children. Therefore, diagnosis of our affected child is not important.
5. I am opposed to sterilization and/or abortion. Therefore, I do not need genetic counseling.
6. If I had only taken better care of myself during pregnancy, my child would not have had Down syndrome.

From the Division of Genetics, Department of Pediatrics, University of North Carolina School of Medicine, Chapel Hill 27514.

1. Not Genetic?

A potentially tragic misconception is the belief that an abnormality is not genetic or hereditary if it seems to have occurred in the family for the first time. Achondroplasia is one of the more common types of dwarfing. Achondroplastic people usually have normal intelligence. They have heads and trunks of normal size, but short extremities. When a child is the first person in the family to be born with achondroplasia, there is almost no chance that a future brother or sister of the affected child will be similarly affected. Yet there will be a 50:50 chance for achondroplasia in each child of the achondroplastic person. The opposite is true for disorders belonging to the large group known as autosomal recessive conditions. Of the 1500 or more hereditary disorders, one third belong to this group.[1] Examples are cystic fibrosis, sickle cell disease, and albinism. When a child is born with one of the autosomal recessive conditions, there are usually no affected parents, uncles, aunts or cousins. Similarly, the chances are very low that the affected child will have an affected offspring in later years. Yet the odds are 25% that a future brother or sister will have the same problem.

2. Bad Stock?

In many instances, indeed in most instances, the parents of a genetically abnormal child do not have a greater number of abnormal genes or chromosomes than do the rest of us, even if the parents have a higher-than-average risk for producing an affected child. We suspect, for example, that each one of us carries three to five genes for severe recessive diseases. If this makes you feel insecure, just remember that we have thousands of genes or hereditary units for controlling our bodily processes — so we can take comfort in knowing that we are at least 99.9% perfect. What saves us from having a recessive disease is the dual nature of genetic control. Your blood type is under dual control. It is determined by one blood type gene from your mother; the other, from your father. Just as the co-pilot can fly and land a jetliner if the pilot becomes ill, our body remains free of recessive disease if only one of the dual genes is defective. If a couple happen by chance to be both carrying the same type of defective gene for a recessive disease, however, there would be a 25% chance that their child would receive the defective gene from both parents. The situation then becomes comparable to an airliner in which neither the pilot nor copilot is functional. The unfortunate thing about the recessive diseases, therefore, is that the parents, by chance, happen to match up for carrying the same type of defective gene — a coincidence comparable to a husband and wife having the same birthday.

A similar situation exists for many of the chromosome abnormalities. Chromosomes are the microscopic particles containing the genes. There are 23 pairs of chromosomes in the cells of normal people. We receive one chromosome of each pair from our mother, the other from our father. Occasionally, an infant receives either a surplus or a deficit of chromosomal material in the reproductive cells from which the infant is conceived. In the case of surplus chromosomal material, there need not be anything wrong with the genes on the extra chromosome. Even if there were, an examination of the chromosomes under the microscope would not usually reveal the abnormal genes. But the surplus genetic instruction becomes a matter of too many cooks spoiling the soup. A surplus or deficit of chromosomal material usually results in malformations and mental retardation. One example of such a chromosomal abnormality is Down syndrome. Children with Down syndrome, which was formerly called mongolism, are mentally retarded but generally good-natured and well-behaved children.

For the most common type of Down syndrome, the parents have normal chromosomes. They should not feel, therefore, that their chromosomes are any more abnormal than those of other parents in the population. If the parents have normal chromosomes, how then did they come to have a child with the extra chromosome? As each cell of the body is about to divide, the cell has a difficult task of duplicating the chromosomes and parcelling them equally between the resulting cells. This is a complicated process with an intrinsic rate of error. As might be imagined, a small percentage of the cells in our body will end up with one too many or one too few chromosomes. This is also true of our reproductive cells. Each of us has a small fraction of reproductive cells with an abnormal number of chromosomes. The child with Down syndrome was unfortunate enough to have been conceived from such a reproductive cell. By the luck of the draw, your own child could have been conceived with an extra chromosome. One illustration of how readily this occurs among chromosomally normal parents is the finding that nearly half of all miscarriages represent chromosomally abnormal embryos. If we assume that some 20% of conceptions end up as miscarriages, then we realize that about 10% of all conceptions result in embryos with an abnormal number of chromosomes. We should not think that parents of genetically abnormal children always have normal genes and chromosomes, but we should remember that for some of the more common types of genetic problems the genes and chromosomes of the parents are as normal as those of the average person.

Nor should we suspect that such parents come from some genetically blighted ethnic group if the parents happen to belong to an ethnic group different from our own. To be sure, certain genetic diseases are concentrated in specific ethnic groups. Sickle cell disease occurs largely in blacks, Tay-Sachs disease in people of Jewish ancestry, and hemoglobin E disease in Orientals. If you are tempted to take comfort in the fact that you do not belong to any of those groups, and that your ancestors lived in Western Europe, then you might reflect on the fact that your ethnic group is prone to cystic fibrosis, phenylketonuria (PKU) and spina bifida. Name your ethnic background and the medical geneticist will tell you which genetic disorders are particularly prevalent in your group. Moreover, certain genetic problems, such as chromosome abnormalities, seem to be about equally common in all ethnic groups that have been studied. While walking or driving, I have seen people with Down syndrome in such diverse places as Salisbury, England; Assisi, Italy; Boone, North Carolina; and Kunming, China.

3. The Error of Self-diagnosis

Physicians encourage adults to look for early signs of cancer in themselves: women to examine their own breasts for lumps, men and women to notice if blood is present in stools. But physicians do not want their patients to assume, on their own, that the problem does or does not represent cancer. The patients should report their observations to their physicians promptly. Similarly, adults should be alert to the possibility of a genetic disease in their own family and express their concern to their physician, but not attempt to make the diagnosis themselves. With both cancer and genetic disease, keeping quiet can have unfortunate consequences. The consequences can be unfortunate either way. A man might commit suicide, thinking that he is at risk for developing Huntington's disease, which killed his grandfather and apparently killed his mother. Yet reading of the medical records and autopsy results on his mother might reveal that she actually died of alcoholism, not Huntington's disease. Or the opposite might be true. He could mistakenly assume that he and his future children are not at risk because he thought his mother died of alcoholism.

One of the more difficult tasks preceding genetic counseling is distinguishing the condition from ones that may resemble it very closely but have an entirely different mode of inheritance. In general, the diagnosis must be made even more accurately for purposes of genetic counseling than for purposes of routine medical or surgical management and treatment. An example is deafness at birth. Such congenital deafness might be the result of the mother's having had German measles during pregnancy, in which case there would be no increased risk for deafness in future children. Or the deafness might represent an autosomal recessive type of deafness, in which case the risk would be 25%. Yet the day-to-day management of the two types of deafness might be essentially the same. An even more impressive example of the need for distinguishing between subtypes is Down syndrome. With the most common type of Down syndrome, the parents run a 2% risk that a future brother or sister of the affected child will also have Down syndrome. For a less common form of Down syndrome, the risk is 15%; and for a fortunately rare form of Down syndrome, the risk is 100%. The risk can be 2%, 15% or 100%. Yet there is no way by which a physician, even a medical geneticist, can distinguish one type of Down syndrome from the other by physical examination of the affected child. The distinction must be made by examination of the chromosomes in a blood sample from the patient with Down syndrome. If the chromosome examination (karyotype) reveals that the Down syndrome is of the trisomy 21 type, as is usually the case, then no examination of the chromosomes of the parents or other relatives is necessary. It is known that this type of Down syndrome has no strong tendency to occur in the offspring of normal appearing relatives. If the affected child has translocation Down syndrome, however, examination of the chromosomes of the parents and possibly other relatives will reveal exactly which relative, if any, is liable to have an affected child. Antenatal (prenatal) diagnosis would be one of the options available to that relative.

WHY SHOULD WE BE CONCERNED?

Each year in the United States about 250,000 infants are born with birth defects. It is estimated that of the 84,000 children born annually in North Carolina, more than 4,000 will be afflicted with birth defects and other genetic problems. The following table lists the number of North Carolina children born with some genetic conditions.

Down Syndrome	128
Cleft lip or cleft lip and palate	114
Neural Tube Defects (Spina Bifida)	120
Hemoglobinopathies (Sickle Cell, etc.)	185
Cystic Fibrosis	35
Phenylketonuria (PKU)	4
Hypothyroidism	12
Mental Retardation	2512

An estimated 352,000 North Carolinians have a handicapping genetic condition. Birth defects constitute the third most common cause of death up to age 14. It is estimated that 35% of all pediatric hospital admissions and 40% of infant deaths are due to genetic conditions.

4. Diagnosis not important?

This complexity with Down syndrome, incidentally, is the primary reason why medical geneticists believe that all patients with Down syndrome should have their chromosomes examined and, equally importantly, that parents, uncles, and aunts should be told whether or not this is the type of Down syndrome that tends to run in families. Parents of the person with Down syndrome sometimes tragically refuse to allow blood samples to be drawn for chromosome analysis on their son or daughter with Down syndrome. They might refuse such examination because they believe: (a) the diagnosis of Down syndrome is certain, (b) they do not plan to have any more children, (c) they consider the problem to be a personal matter of no concern to others, or (d) "Johnny has already suffered enough." In fact, chromosome analysis is not done just to tell the parents whether or not the child has Down syndrome or even whether or not future brothers and sisters will have the same condition. It is done to tell whether or not future cousins, nephews, and nieces will have the same problem.

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The telephones of the Genetic Counseling Program in Chapel Hill ring from time to time with a call from an obstetrician or family physician wanting to know the diagnosis of a North Carolina child evaluated in our laboratory or clinic. The physician is taking care of the child's aunt or older sister, who lives in Oregon or Texas, and the physician wants to know if this pregnant aunt or sister is at risk for having a similarly affected child. Such telephone calls, which are occurring with increasing frequency, also justify the encouraging of parents to permit autopsy and full diagnostic evaluation of infants who die with malformations or metabolic abnormalities. In the course of normal grief over losing a newborn infant, parents may refuse to allow such evaluations, yet often the parents will return to their physician or hospital in subsequent months or years wanting to know the cause of death, whether the abnormality is likely to occur again and whether antenatal diagnosis or early treatment might prevent a similar outcome. Even when the parents plan to have no more children, the normal aunts, uncles, and older siblings may ask the same question. Sessions on genetics, birth defects, and chromosomes in high school are causing young adults to ask many more questions about such matters than did young adults of earlier decades.

5. Non-directive Nature of Counseling

Most medical geneticists do not advocate that all genetic counseling be done at genetic clinics. The genetic disorders are simply too common to allow this, regardless of whether or not it is desirable. Consequently, the practicing physician will be providing this service in certain instances, especially when he or she has the time and training to distinguish the condition from genetically distinct abnormalities that closely resemble the condition. In the process of explaining the nature of genetic counseling to medical students and physicians, medical geneticists point out that genetic counseling should be non-directive. In contrast to managing a patient with appendicitis or with early signs of meningitis, we do not tell patients what to do. Choosing among the various options that may be possible — having additional children, avoiding childbearing, artificial insemination (for autosomal recessive diseases), antenatal diagnosis (if possible) and selective abortion, early treatment, and adoption — is a personal matter. The choice is best made by the couple, who will after all be the ones who must live with their decision. This is particularly appropriate since one can obtain differences of opinion even among medical geneticists as to which choice is best in a particular instance. It is important that the couple make the decision that they will feel most comfortable living with. The average couple, however, will most certainly need information about how severe or how mild the disease is. An intelligent decision cannot be made without the couple's having a realistic understanding of the emotional and financial burden of the disease on the one hand, or the ease with which it can be treated on the other hand. Most important is that couples not avoid genetic counseling if they are opposed to sterilization or abortion. If they have such oppositions, their options are reduced and their understanding of other options becomes even more important.

6. The Positive Side

All is not doom and gloom in genetic counseling clinics. Nearly half of the couples coming to Chapel Hill learn that their chances of having a normal child are even better than they thought. Those who provide genetic counseling have the pleasure of being able to dispel inappropriate feelings of guilt and blame. Mothers of chromosomally abnormal children, for example, often secretly blame themselves for causing the birth defects of their child. The mother believes that the birth defect was caused by something that she did during the pregnancy — going on a long trip, taking a headache powder. The medical geneticist is able to point out that the chromosomal abnormality was determined at the moment of conception. It was not caused by anything which the mother did or did not do during pregnancy. Mothers-in-law, suspecting that the recessive gene must have been one of those "bad tendencies" coming from the other side of the family, can be reminded that the abnormal genes came from both sides of the family and that they were probably passed in hidden form from one generation to the next for many generations. Studies of certain genetic conditions are revealing the extent to which the bad consequences of the condition can be prevented by early diagnosis and treatment. Diagnosing affected patients in infancy and placing them on special treatment can prevent the mental retardation of PKU, the stunting of growth and bowing of legs of hereditary rickets (a condition particularly common in North Carolina), and the blindness of galactosemia. A blood test on pregnant women, at 16-18 weeks in the pregnancy, will detect about 80-90% of the cases of anencephaly (open skull and absence of brain development) or severe spina bifida. Although those opposed to abortion may object to the availability of this test, they should know that the results of the test strongly determine how and where the woman should deliver the infant, even if she chooses not to have an abortion. Moreover, the introduction of this test in the British Isles, and the simultaneous studies of couples having infants with these defects of skull and spine, resulted in a surprising finding. Such mothers seem to be much less prone to have another affected infant if the mother begins taking a prenatal vitamin tablet, containing folic acid, *before* the next pregnancy. Spina bifida and anencephaly are relatively common in Ireland, Scotland, and England. Perhaps the occurrence of these birth defects in white people of North Carolina is due in part to the Irish, Scottish, and English ancestry of many of the people of North Carolina. Whether this vitamin approach will prevent anencephaly and spina bifida in the United States remains to be determined, but this happy development in the British Isles serves to illustrate how much the approach to genetic conditions can differ from the grim features that one might suspect.

In addition, the field of medical genetics is not becoming just another super-specialty in medicine. It is forcing each physician to become a bit more of a generalist. The dislocated lens of the eye, which the ophthalmologist sees, may represent a condition known as Marfan syndrome, which requires the attention of family physicians and cardiologists. The urologist who diagnoses a patient as having kidney stones due to cystinuria is obliged to remember that sisters and brothers can also be affected with this condition, for which prevention and medical treatment of the stones are possible. Finally, advances in understanding genetic diseases enable family physicians to live up to their namesake. The development of the field of medical genetics, therefore, is a trend that will cause a broadening and interaction of the various fields of medicine in a manner that some of us find to be most welcome.

Medical Genetics in North Carolina

When giving out-of-state lectures about medical genetic problems in North Carolina, I am often approached afterword by physicians who ask how North Carolina came to have more genetic problems than other states. The answer, of course, is that North Carolina probably does not have more genetic problems than other states. Those physicians are simply unaware of the extent to which genetic problems are present in their own state. Few of us realize that there is a national award for teaching and research in human genetics. This award, given periodically at annual meetings of the American Society of Human Genetics, is called the William Allan Award.[2] It is named after a North Carolina physician, William Allan (1881-1943), who carried out some of the earliest observations on the genetic nature of certain human diseases. During the 1960s, North Carolina was criticized for not adopting a bacterial method for checking newborn infants for the condition known as phenylketonuria (PKU). Newborn infants in North Carolina and most other states are tested for this condition routinely. If the affected infant is diagnosed and started on a special diet soon after birth, the infant is spared from developing severe mental retardation. Rather than use the bacterial method, health officials of North Carolina adopted[3] an automated fluorometric method de-

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veloped by two North Carolina physicians, Dr. John Hill and Dr. George Summer. This method is proving to be more accurate than the bacterial method. Health officials in certain states, where North Carolina was criticized, are beginning to switch to the automated fluorometric method.

Moreover, on a per capita basis, North Carolina is unusually well represented in the directory of people who have successfully passed a board certification examination that was recently given by the National Board of Medical Examiners and by the new American Board of Medical Genetics. With the inclusion of people who have completed their training and have gone to other medical centers, the directory contains an impressive number of names of people from North Carolina and especially from Chapel Hill. North Carolina was one of the first states to provide state funds for genetic clinics, including clinics where genetic counseling would be available to people least able to afford the counseling, such as young couples whose savings were depleted by a lengthy hospitalization of their first child. March of Dimes funds and State funds also provided for clinics in other North Carolina cities to which physicians from the medical school in Chapel Hill could fly to assist in the diagnosis and counseling of families with genetic disorders. Such out-of-town clinics are being held also by the staff of Bowman Gray Medical School. One or more people, board certified in medical genetics, can be found on the staff of Charlotte Memorial Hospital and at each of the four medical schools in North Carolina.

Additional Reading

You will find more details on the subject of genetic diseases in *The Genetic Connection. How to Protect Your Family Against Hereditary Disease,* by David Hendin and Joan Marks.[4] An excellent 22-page pamphlet, *Genetic Counseling*, is available through the March of Dimes Birth Defects Foundation in Raleigh (Mr. Jack McGee, P.O. Box 10691, Raleigh 27605) or through your local March of Dimes Office. In addition, a short pamphlet, *All About Genetic Services*, can be obtained from the Division of Health Services, Department of Human Resources, P.O. Box 2091, Raleigh 27602.

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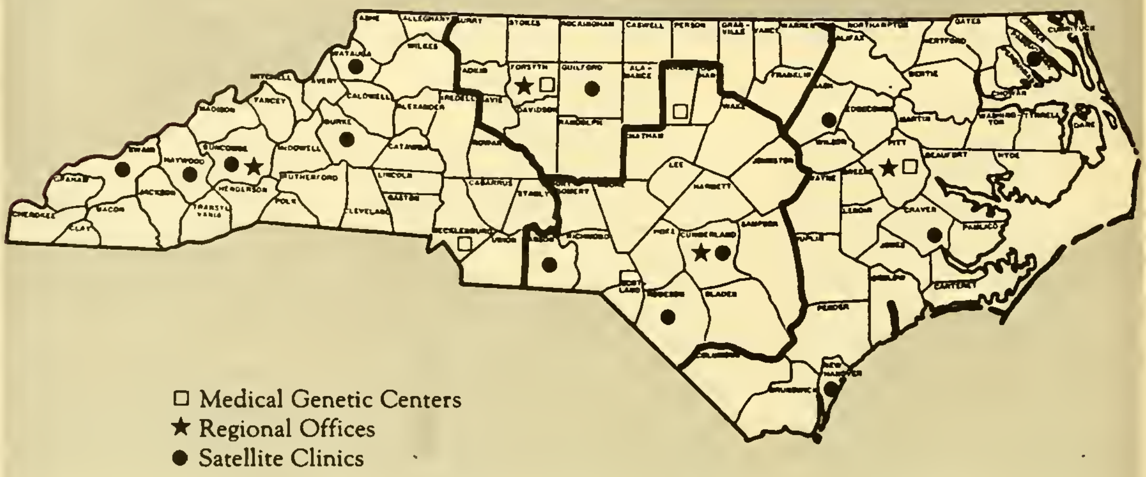
NORTH CAROLINA GENETIC SERVICES



Rocky Mountain Spotted Fever

Claude S. Burton, M.D., Peter W. Heald, M.D., and J. Lamar Callaway, M.D.

This is one disease that could have been called North Carolina Tick Typhus had it not been first discovered in the Rocky Mountains of Montana. North Carolina leads the world in cases of Rocky Mountain Spotted Fever (RMSF) and tragic fatalities occur often. The number one cause of death is delay in diagnosis. Though we don't need the notoriety of such a frequently tragic disease, too little attention has been given to informing our citizens about RMSF.

A bacterium known as rickettsia rickettsii (named for Dr. Howard T. Ricketts, the discoverer of the organism) is responsible for the disease. The bacteria live in the tick and are excreted in tick droppings and saliva. Man becomes infected when bitten by an infected tick and by direct contact with the rickettsiae through openings in the skin (i.e., when removing ticks). Human infection has also occurred by aerosol transmission to laboratory workers studying the disease. Fortunately not all ticks carry RMSF. A study of Piedmont, N.C. ticks found that less than 1 in every 1000 ticks were carrying the bacteria. Since ticks often crawl about for a few hours before biting, one may remove the pest before inoculation occurs. Therefore, a fear of ticks is unwarranted and the threat of RMSF shouldn't keep us from enjoying the woodlands. Not all ticks that harbor bacteria are equally virulent. For reasons that are not clear, exposure to a blood meal renders the bacteria much more likely to produce serious disease. The incubation period varies from 3 to 14 days. The shorter the incubation the more serious the disease.

Doctors and patients invest too much importance in a history of tick exposure when considering whether or not they are dealing with RMSF. Never be misled by the lack of a tick history. Half of the patients with RMSF deny tick exposure. Ticks are often found in most unlikely places including nursing homes, department stores and even hospitals. Virtually everyone reading this article has been exposed. Enough about ticks. A patient recently admitted to our hospital after accidental thumb amputation developed a rash several days after hospitalization. What was thought to be a drug related rash proved on biopsy to be RMSF! Though the illness was most likely in the incubation phase when the patient was admitted to the hospital, this case emphasizes the need to be constantly on the alert, even in unlikely circumstances. Cases have even been reported from blood transfusion.

The early symptoms of RMSF are common to many diseases. Fever is the only consistent finding and may be masked by aspirin or Tylenol. The rash is not present in all cases and may be so obscure that a magnifying glass is necessary to identify its presence. The rash is of enormous benefit if present and biopsy of the rash often establishes the diagnosis. In certain high risk groups (over 50, blacks) the rash is often a late sign associated with a guarded prognosis. In view of the frequently obscure and occasionally absent rash, neither patients nor doctors should rely on this criterion. Frequently noted symptoms include headache, nausea, vomiting, and cramps. However, the list of reported symptoms is virtually endless. Common misdiagnoses are "flu" and "viral syndrome."

The diagnosis of RMSF should be carefully considered in anyone with fever during the tick season. If there is any doubt, doctors should err on the side of overtreatment. The drugs used to treat the disease have rare side effects whereas missing a case of RMSF may prove fatal to the patient. Only tetracycline and chloramphenicol are effective against RMSF. Tetracycline is the drug of choice for adults but stains the teeth of children. Chloramphenical doesn't stain the teeth but is on very rare occasion associated with fatal suppression of the bone marrow. For this reason a five day course of tetracycline is suggested for a febrile illness in children lasting more than two days. No fatalities occur in animals with RMSF treated with tetracycline early in their illness. We are often asked, "Why not take one of these drugs prophylactically if you are bitten by a tick?" Interestingly, such an approach doesn't work. Until the patient's defense mechanisms mount to fight the infection, the bacteria proliferate, despite antibiotics.

During the tick season check yourself, your children, and your pets for ticks. Fat fertile female ticks may drop from your pet to lay thousands of eggs. Since infected ticks pass the organism to their offspring, a house may become infested with infective ticks. There are several reports of multiple members of a family developing RMSF. When removing ticks, prevent self-inoculation by using tweezers, paper napkins, etc. Avoid areas of heavy infestation. Drag a cloth around an area before picnicking to check the tick population. If you find ticks in great numbers, move.

Most importantly, seek medical advice for any fever during the tick season and ask specifically about RMSF. No one need ever die of this disease.

IT'S GETTING TOUGHER FOR NANCY RAY TO BE A MOTHER.

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(BRIEF SUMMARY)

DESCRIPTION
Each tablet contains 200 mg meprobamate and 325 mg aspirin

INDICATIONS
Adjunct in short-term treatment of pain accompanied by tension and or anxiety in patients with musculoskeletal disease Clinical trials demonstrated that in these situations relief of pain is somewhat greater than with aspirin alone Effectiveness in long-term use i e over 4 months, has not been assessed by systematic clinical studies Physicians should periodically reassess usefulness of drug for individual patients

CONTRAINDICATIONS
ASPIRIN Allergic or idiosyncratic reactions to aspirin or related compounds

MEPROBAMATE Acute intermittent porphyria allergic or idiosyncratic reactions to meprobamate or related compounds e g carisoprodol mebutamate or carbromal

WARNINGS
ASPIRIN Use salicylates with extreme caution in patients with peptic ulcer, asthma coagulation abnormalities, hypoprothrombinemia vitamin K deficiency or those on anticoagulants In rare instances aspirin in persons allergic to salicylates may result in life threatening allergic episodes

MEPROBAMATE DRUG DEPENDENCE Physical and psychological dependence and abuse have occurred Chronic intoxication from prolonged ingestion of usually greater than recommended doses is manifested by ataxia slurred speech and vertigo Therefore carefully supervise dose and amounts prescribed and avoid prolonged use especially in alcoholics and others with known propensity for taking excessive quantities of drugs Sudden withdrawal after prolonged and excessive use may precipitate recurrence of preexisting symptoms, e g anxiety, anorexia or insomnia or withdrawal reactions, e g vomiting ataxia tremors muscle twitching confusional states, hallucinosis, and, rarely, convulsive seizures Such seizures are more likely in persons with CNS damage or preexistent or latent convulsive disorders Onset of withdrawal symptoms occurs usually within 12 to 48 hours after discontinuation, symptoms usually cease within next 12- to 48-hour period When excessive dosage has continued for weeks or months, reduce dosage gradually over 1 to 2 weeks rather than stop abruptly Alternatively a short acting barbiturate may be substituted then gradually withdrawn

POTENTIALLY HAZARDOUS TASKS Warn patients meprobamate may impair mental or physical abilities required for potentially hazardous tasks e g driving or operating machinery

ADDITIVE EFFECTS Since CNS-suppressant effects of meprobamate and alcohol or meprobamate and other psychotropic drugs may be additive exercise caution with patients taking more than one of these agents simultaneously

USAGE IN PREGNANCY AND LACTATION
An increased risk of congenital malformations associated with minor tranquilizers (meprobamate, chlordiazepoxide, and diazepam) during first trimester of pregnancy, has been suggested in several studies Because use of these drugs is rarely a matter of urgency, their use during this period should almost always be avoided The possibility that a woman of childbearing potential may be pregnant at time of institution of therapy should be considered Advise patients if they become pregnant during therapy or intend to become pregnant to communicate with their physicians about desirability of discontinuing the drug

Meprobamate passes the placental barrier It is present both in umbilical-cord blood at or near maternal plasma levels and in breast milk of lactating mothers at concentrations two to four times that of maternal plasma When use of meprobamate is contemplated in breastfeeding patients, consider the drug's higher concentrations in breast milk as compared to maternal plasma levels

USAGE IN CHILDREN Keep preparations with aspirin out of reach of children Equagesic® (meprobamate with aspirin) is not recommended for patients 12 years of age and under

PRECAUTIONS:
ASPIRIN Salicylates antagonize uricosuric activity of probenecid and sulfinpyrazone Salicylates are reported to enhance hypoglycemic effect of sulfonylurea antidiabetics

MEPROBAMATE Use lowest effective dose particularly in elderly and/or debilitated to preclude over-sedation Meprobamate is metabolized in the liver and excreted by the kidney to avoid excess accumulation exercise caution in its use in patients with compromised liver or kidney function Meprobamate occasionally may precipitate seizures in epileptic patients It should be prescribed cautiously and in small quantities to patients with suicidal tendencies

ADVERSE REACTIONS
ASPIRIN May cause epigastric discomfort nausea and vomiting Hypersensitivity reactions, including urticaria, angioneurotic edema, purpura asthma and anaphylaxis may rarely occur Patients receiving large doses of salicylates may develop tinnitus

MEPROBAMATE CNS Drowsiness, ataxia, dizziness, slurred speech, headache vertigo, weakness paresthesias, impairment of visual accommodation, euphoria, overstimulation, paradoxical excitement, fast EEG activity

GI Nausea, vomiting, diarrhea

CARDIOVASCULAR Palpitation, tachycardia, various forms of arrhythmia transient ECG changes syncope, hypotensive crisis

ALLERGIC OR IDIOSYNCRATIC Milder reactions are characterized by itchy urticarial or erythematous maculopapular rash, generalized or confined to the groin Other reactions include leukopenia, acute nonthrombocytopenic purpura petechiae, ecchymoses, eosinophilia peripheral edema, adenopathy, fever fixed drug eruption with cross-reaction to carisoprodol and cross-sensitivity between meprobamate/mebutamate and meprobamate carbromal Rare more severe hypersensitivity reactions include hyperpyrexia chills, angioneurotic edema, bronchospasm, oliguria, and anuria Also anaphylaxis, exfoliative dermatitis, stomatitis and proctitis Stevens-Johnson syndrome and bullous dermatitis have occurred

HEMATOLOGIC (SEE ALSO "ALLERGIC OR IDIOSYNCRATIC") Agranulocytosis, aplastic anemia have been reported, although no causal relationship has been established, and thrombocytopenic purpura

OTHER Exacerbation of porphyric symptoms

DOSAGE AND ADMINISTRATION:
Usual dose is one or two tablets 3 to 4 times daily as needed for relief of pain when tension or anxiety is present Not recommended for patients 12 years of age and under

OVERDOSAGE:
Treatment is essentially symptomatic and supportive Any drug remaining in the stomach should be removed Induction of vomiting or gastric lavage may be indicated Activated charcoal may reduce absorption of both aspirin and meprobamate Aspirin overdosage produces usual symptoms and signs of salicylate intoxication Observation and treatment should include management of hyperthermia, specific parenteral electrolyte therapy for ketoacidosis and dehydration, watching for evidence of hemorrhagic manifestations due to hypoprothrombinemia which, if it occurs, usually requires whole-blood transfusions Suicidal attempts with meprobamate have resulted in drowsiness lethargy, stupor ataxia coma shock vasomotor and respiratory collapse Some suicidal attempts have been fatal The following data reported in the literature and from other sources, are not expected to correlate with each case (considering factors such as individual susceptibility and length of time from ingestion to treatment) but represent usual ranges reported Acute simple overdose (meprobamate alone) Death has been reported with ingestion of as little as 12 grams meprobamate and survival with as much as 40 grams

BLOOD LEVELS
0 5-2 0 mg percent represents usual blood level range of meprobamate after therapeutic doses The level may occasionally be as high as 3 0 mg percent

3-10 mg percent usually corresponds to findings of mild-to-moderate symptoms of overdosage, such as stupor or light coma

10-20 mg percent usually corresponds to deeper coma, requiring more intensive treatment Some fatalities occur

At levels greater than 20 mg percent, more fatalities than survivals can be expected

Acute combined overdose (meprobamate with other psychotropic drugs or alcohol) Since effects can be additive history of ingestion of a low dose of meprobamate plus any of these compounds (or of a relatively low blood or tissue level) cannot be used as a prognostic indicator

In cases of excessive doses, sleep ensues rapidly and blood pressure pulse, and respiratory rates are reduced to basal levels Any drug remaining in stomach should be removed and symptomatic treatment given Should respiration or blood pressure become compromised, respiratory assistance CNS stimulants and pressor agents should be administered cautiously as indicated Diuresis, osmotic (mannitol) diuresis peritoneal dialysis, and hemodialysis have been used successfully in removing both aspirin and meprobamate Alkalinization of the urine increases excretion of salicylates Careful monitoring of urinary output is necessary and caution should be taken to avoid overhydration Relapse and death, after initial recovery have been attributed to incomplete gastric emptying and delayed absorption

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Beware The Xanthines Bearing Gifts: Theophylline Overdose

Ronald B. Mack, M.D.

ONE of my favorite stories involves the Trojan Horse, as told in Virgil's *Aeneid*. One of the many lessons it should teach us, as health care professionals, is that nothing is ever exactly as it seems; you must be skeptical enough to ask lots of questions before accepting only what appears to be obvious.

The Ancient Greeks talked a lot about *hubris* — overwhelming pride or presumption — it often led to the tragic fall of a hero. After fighting the Trojans for 10 years, the Greeks decided to leave Troy and return home. In their place they built a very large wooden horse filled with warriors which they alleged was an offering to the goddess Minerva to ensure their safe passage home. The Trojans, suffering from acute hubris, decided to take the horse into the city — they were so proud of themselves after the Greeks retreated. There was at least one hero in this tragic story and his name was Laocoon. This fellow was a priest of Apollo's Temple and he tried to warn his countrymen against the dangers of this gigantic wooden beast whose insides he considered potentially bad news indeed. Nobody listened to this poor fellow and he and his two young sons were strangled and crushed to death by two horrible sea serpents who rose from the waves and did them in. The rest is history as they say. Let me therefore warn you about the dangers of theophylline. I do this without hubris and with a good supply of sea serpent antivenom on hand.

Theophylline is a drug in very common use for treating acute and chronic pulmonary problems. If you take care of sick children and/or sick adults the chances are you use a fair amount of this product. It's hard to pick up a medical journal these days that doesn't have a new article on theophylline therapy or an advertisement on a new theophylline preparation. You must realize that theophylline, as useful as it may be, has a very narrow therapeutic range and overdosage can be a tremendous problem for the patient and the clinician.

Fortunately a lot is known about this drug in terms of pharmacokinetics, and blood levels are quite readily attainable. Most of the following data does not apply to the slow release preparations. Theophylline is a methylxanthine which is quite rapidly and efficiently absorbed from the GI tract when taken per os, with peak blood levels occurring within 2 hours of ingestion. About ½ to ⅔s of theophylline is bound to protein. The volume of distribution (V_D) is 0.5 L/kg and au courant readers will immediately see this drug's potential for extracorporeal removal in case of serious overdose. As with many drugs, age of the patient is a prominent feature in this drug's metabolism. Thus, clearance of this medication progressively increases and the half life (T½) decreases from birth to about 9 months of age. Maximal clearance is thought to be achieved during the ages 1 to 9 years. After 9-10 years of age clearance decreases into adolescence and tends to stabilize in the mid-teen years. At therapeutic levels the T½ also varies with age, going from 20 hours ± in the full-term newborn to 6-7 hours in the first 6 months of life to 3.5 to 5 hours from 1 to 18 years and finally 4.5-5 hours for adults. About 95% of theophylline is metabolized by the liver following first order kinetics (elimination is directly proportional to the amount of drug remaining) at therapeutic levels and first order and zero order kinetics (zero order kinetics = elimination that occurs at a fixed rate regardless of the amount of drug remaining) in overdose situations. To put it more succinctly, the T½ varies quite a lot depending on age group, other diseases or other drugs on board at the same time, etc. The T½ in normal and asthmatic adults has a mean of approximately 5.8 hours and in children, a mean half life of about 3.69 hours.

Theophylline is really a neat drug in terms of its action. We know that it relaxes bronchial smooth muscle (of course that's why you give the drug. What did you think it was, an aphrodisiac?). Theophylline is involved with cyclic AMP (this is not a gossip item, it's the truth). Cyclic AMP has to do with the release or inhibition of "mediators" that can affect bronchial smooth muscle, among other things. If you can increase the cyclic AMP you can inhibit these mediators and that's good. Cyclic AMP is degraded by the enzyme phosphodiesterase and theophylline inhibits this enzyme and thus cyclic AMP increases and that's really good if you have asthma. This drug may also inhibit some *prostaglandin* activity and thereby lessen contraction of bronchial smooth muscle. Some authors believe that the drug may enhance catecholamine activity. No matter how it works, it can dramatically change the life of a stricken asthmatic if given in the correct dose for the patient.

In the event of overdose, either due to "therapeutic misadventure" or accidental ingestion or even purposeful ingestion, the consequences can be awesome. The evil effects can range from a little headache and bellyache to coma and seizures and even death. We are all aware by now that you should aim for a therapeutic blood level of *10-20 μg/ml*. Toxicity appears to be related to the serum concentration, e.g., *mild* toxicity can be seen at a serum level of *20-40 μg/ml* and *severe* toxicity at *40-80 μg/ml*. However, bear in mind that mild symptoms can occur even at therapeutic theophylline levels and children seem to be more tolerant to toxic levels of this drug. The *CNS*, *GI*, and *cardiovascular* systems are the main target organs in a theophylline overdose.

Before we begin to think about the specific effects that occur in a theophylline overdose some thought should be given to the *physiological* effects of theophylline as opposed to the *pathophysiological* effects. The "Trojan Horse" phenomenon might be seen here because knowing the physiological effects of the xanthines can help you to predict the powerful clinical results resulting from overdose. Let's try to "empty the horse" to see what the extent of damage could be when the drug is used unwisely. (Is this analogy too arcane? Did I lose many of you? I'm sorry!!) The xanthines, especially drugs like theophylline, can stimulate the cortex and medulla and have secondary effects as a result of such CNS stimulation on skeletal muscle, cardiovascular, respiratory and gastrointestinal systems. As a primary action on the *cardiovascular* system there is an increased rate (chronotropic) and force (inotropic) of cardiac contractions. The gastrointestinal tract responds by increasing gastric acid and pepsin secretion. There is increased renal blood and diuresis with theophylline use but the good news is that this drug relaxes bronchial smooth muscle and increases ventilation and that's great because that's probably the reason you used the stuff in the first place. Theophylline produces many other effects that you may or may not want your patient to endure such as a decrease in potassium and an increase in both lipolysis and glycogenolysis and catecholamine release.

In theophylline overdose in a mild case (20-40 μg/ml ±) the patient may only complain of headache and insomnia plus palpitations, anorexia, nausea, vomiting, and abdominal pain and exhibit tremors and tachycardia. In more advanced overdose situations the patient is confused, maniacal or stuporous and has more vomiting and diarrhea and can be quite tachypneic. In severe theophylline overdose (40-80 μg/ml) we are talking big trouble. It is even more frightening to face the prospect that the milder effects of overdose may not necessarily precede the life threatening features of coma, seizures, GI bleeding, hyperthermia, cardiac arrhythmias and shock in about one-half of the cases. Seizures seem to be more common when the serum theophylline level rises above 50 μg/ml. Although generalized seizures are the more typical cerebral dysrhythmic response, focal seizures may occur. Tachycardia is thought to be the most universal sign of theophylline poisoning. Cardiovascular collapse is not common with serum concentrations below 50 μg/ml.

Knowing what we now have learned about theophylline overdose, the work-up becomes somewhat easier to figure out and should include a theophylline level, an EKG, a hemoglobin and crit, serum potassium level, arterial blood gases, chest x-ray and an examination of gastric contents and stool for blood. For the best results, using current technology, measure serum theophylline by high pressure liquid chromatography as it is the *most accurate* so far. In an acute overdose situation, *take more than one level* before you decide that the overdose was or was not significant and this is especially true in suspected overdose from slow release theophylline preparations. Serial theophylline levels will help you to determine the elimination rate as well, which could help you determine how long your patient was subjected to a toxic level. Let me emphasize again that with very large overdoses or the ingestion of sustained release theophylline preparations at least two specimens, 4 hours apart, should be obtained for serum theophylline concentration.

The treatment of theophylline overdose is not as futile as with some other toxins and some new therapeutic modalities make efficient therapy potentially available to even some of the smaller hospitals. You have to empty the patient's stomach — not much argument here — by either the use of ipecac or gastric lavage depending on the patient's level of consciousness. Gastric contamination should be performed almost regardless of the probable ingestion time. The administration of activated charcoal is of paramount importance and should be followed by a saline cathartic. One of the newest suggested methods to "deactivate" the ingested theophylline is to administer repeated doses of activated charcoal. It is believed that this charcoal not only stops further absorption of the theophylline that remains in the GI tract but apparently absorbs theophylline from the bloodstream across the capillary bed of the small intestine. This, in my opinion, is a very exciting breakthrough as it is relatively benign, fairly easy to do and obviates the need for specialized equipment. Theophylline is very well absorbed by activated charcoal. The activated charcoal should be administered about every 4 to 6 hours until the serum theophylline level decreases below 40-60 μg/ml. This method should decrease the T½. It is probably a good idea to give a saline cathartic with each dose of charcoal because if you don't the patient might have great difficulty "passing" the charcoal and will end up with material that is only suitable for use as an outdoor cooking material for barbecues.

Seizures, more so in adults than in children, can be a real headache to the "treater" as well as the treated. They seem to be more common with serum theophylline levels above 50 μg/ml and can be terminated with parenteral diazepam or barbiturates or phenytoin. *Hypotension* not responding to intravenous fluids can be combatted with pressor agents, e.g., norepinephrine or dopamine. You can give propranolol or digoxin for *supraventricular rhythm* disturbances and lidocaine or propranol or phenytoin for *ventricular arrhythmias*. Pronounced *GI bleeding* should be treated in the conventional manner with IV fluids and blood. Unfortunately, fluid diuresis is not very effective in removing theophylline from the body. Pay careful attention to potassium levels and needs.

In very severe cases of theophylline overdose there is, fortunately, a possible life-saving therapeutic modality — extracorporeal removal. That is to say, you can remove theophylline via dialysis (either peritoneal or hemo) or hemoperfusion. There is no question in my mind, at least with current knowledge, that hemoperfusion is the way to go. Theophylline lends itself nicely to this procedure; the volume of distribution is only 0.5 L/kg. Charcoal or resin hemoperfusion can remove considerably more theophylline than the other currently used extracorporeal methods. There are probably no absolute levels of theophylline that mandate use of hemoperfusion but intractable cases of arrhythmia or coma or hypotension or seizure should be considered as candidates. Some authors suggest hemoperfusion at levels of 100 μg/ml for acute overdose and 60-80 μg/ml for the slow release theophylline preparations. It has recently been recommended that extracorporeal measures should be used in pediatric patients who fail to respond to more conservative methods or whose serum concentrations exceed 80-100 μg/ml. A new experimental regimen, only tried in a small number of patients so far, suggests that propranolol may be the ''antagonist'' of choice and *could* be considered in those patients who are ''too sick'' to be hemoperfused.

I must leave quickly now, I've warned you and I now see two giant sea serpents being brought into our clinic in a Winn-Dixie shopping bag and frankly I am scared. Quickly nurse, get me my anti-hubris pills and sea serpent antivenom.

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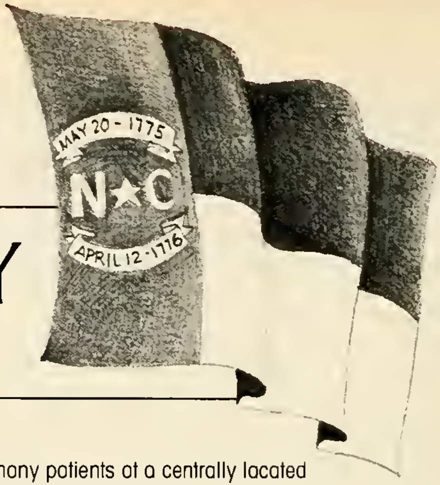


THE 18-HOUR-A-DAY DOCTOR

Dr. Gaine Cannon

A modern-day version of the country doctor on horseback, Dr. Gaine Cannon covered his scattered practice around the Blue Ridge Mountain country near Balsam Grove, North Carolina, in a four-wheel-drive Jeep wagon.[1]

On an average working day, Dr. Cannon rose at sunup to see patients at his converted-farmhouse clinic before setting out to make his usual 15 to 20 house calls around the countryside. Generally, after treating his primary patient, he saw each member of the family as well—his personal effort at preventive medicine.

Multiple services

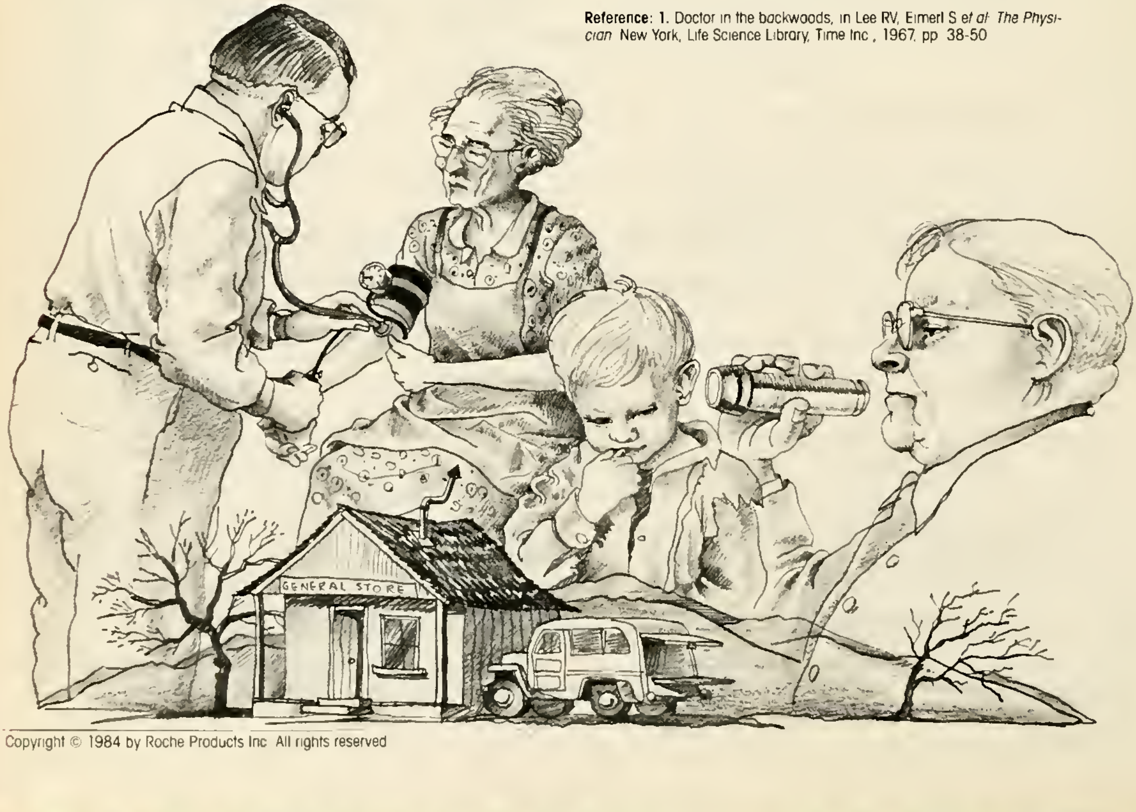
With the nearest hospital some 60 miles away and no pharmacy closer than an hour-and-a-half drive, Dr. Cannon filled his own prescriptions, delivered babies and treated many patients at a centrally located general store with the most modern techniques and medications. After a day on the road—usually within a 50-mile radius—Dr. Cannon's office hours would begin at 5:30 p.m. and stretch on until the last patient was attended to. His record-keeping sessions routinely filled the hour before midnight—rounding off Dr. Cannon's 18-hour day.

At all hours

But emergencies often interrupted his sleep. Dr. Cannon claimed his real office hours were 24 hours a day, and his patients revered him for it.

Dr. Cannon died in 1966 at the age of 68. He will be long remembered—most especially by the more than 5000 North Carolinians he helped bring into the world, some of them at the side of a rutted country road.

Reference: 1. Doctor in the backwoods, in Lee RV, Eimerl S *et al*: *The Physician*. New York, Life Science Library, Time Inc, 1967, pp 38-50



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62% of Overall Improvement...Within the First Week

Limbitrol also has a rapid onset of action which may lead to greater patient compliance. In a multicenter study, patients taking Limbitrol experienced 62% of their overall improvement within the first week of therapy.[2]

In another multicenter study,[3] the following symptoms associated with anxious depression were significantly reduced during the first two weeks of therapy:

- ☐ Headache—79%
- ☐ Early insomnia—91%
  Middle insomnia—87%
  Late insomnia—89%
- ☐ Gastrointestinal upset—73%

In two multicenter studies, only 1.9% of Limbitrol patients experienced cardiovascular side effects.[3]

Patients should be cautioned about the combined effects with alcohol or other CNS depressants and about activities requiring complete mental alertness such as operating machinery or driving a car.

References: **1.** Rickels K. Drug treatment of anxiety, in *Psychopharmacology in the Practice of Medicine*, edited by Jarvik ME; New York, Appleton-Century-Crofts, 1977, p 316. **2.** Feighner JP *et al: Psychopharmacology 61*:217-229, Mar 1979. **3.** Data on file, Hoffmann-La Roche Inc., Nutley, NJ.

In moderate depression and anxiety

Limbitrol® Ⓒ IV

Tablets 5-12.5 each containing 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt)

Tablets 10-25 each containing 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt)

Please see summary of product information on following page.

LIMBITROL® Tablets Ⓒ Tranquilizer–Antidepressant

Before prescribing, please consult complete product information, a summary of which follows:

Indications: Relief of moderate to severe depression associated with moderate to severe anxiety.

Contraindications: Known hypersensitivity to benzodiazepines or tricyclic antidepressants. Do not use with monoamine oxidase (MAO) inhibitors or within 14 days following discontinuation of MAO inhibitors since hyperpyretic crises, severe convulsions and deaths have occurred with concomitant use, then initiate cautiously, gradually increasing dosage until optimal response is achieved. Contraindicated during acute recovery phase following myocardial infarction.

Warnings: Use with great care in patients with history of urinary retention or angle-closure glaucoma. Severe constipation may occur in patients taking tricyclic antidepressants and anticholinergic-type drugs. Closely supervise cardiovascular patients. (Arrhythmias, sinus tachycardia and prolongation of conduction time reported with use of tricyclic antidepressants, especially high doses. Myocardial infarction and stroke reported with use of this class of drugs.) Caution patients about possible combined effects with alcohol and other CNS depressants and against hazardous occupations requiring complete mental alertness (*e.g.*, operating machinery, driving).

> ***Usage in Pregnancy:*** **Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.**

Since physical and psychological dependence to chlordiazepoxide have been reported rarely, use caution in administering Limbitrol to addiction-prone individuals or those who might increase dosage; withdrawal symptoms following discontinuation of either component alone have been reported (nausea, headache and malaise for amitriptyline; symptoms [including convulsions] similar to those of barbiturate withdrawal for chlordiazepoxide).

Precautions: Use with caution in patients with a history of seizures, in hyperthyroid patients or those on thyroid medication, and in patients with impaired renal or hepatic function. Because of the possibility of suicide in depressed patients, do not permit easy access to large quantities in these patients. Periodic liver function tests and blood counts are recommended during prolonged treatment. Amitriptyline component may block action of guanethidine or similar antihypertensives. Concomitant use with other psychotropic drugs has not been evaluated; sedative effects may be additive. Discontinue several days before surgery. Limit concomitant administration of ECT to essential treatment. See Warnings for precautions about pregnancy. Limbitrol should not be taken during the nursing period. Not recommended in children under 12. In the elderly and debilitated, limit to smallest effective dosage to preclude ataxia, oversedation, confusion or anticholinergic effects.

Adverse Reactions: Most frequently reported are those associated with either component alone: drowsiness, dry mouth, constipation, blurred vision, dizziness and bloating. Less frequently occurring reactions include vivid dreams, impotence, tremor, confusion and nasal congestion. Many depressive symptoms including anorexia, fatigue, weakness, restlessness and lethargy have been reported as side effects of both Limbitrol and amitriptyline. Granulocytopenia, jaundice and hepatic dysfunction have been observed rarely.

The following list includes adverse reactions not reported with Limbitrol but requiring consideration because they have been reported with one or both components or closely related drugs:

Cardiovascular: Hypotension, hypertension, tachycardia, palpitations, myocardial infarction, arrhythmias, heart block, stroke.

Psychiatric: Euphoria, apprehension, poor concentration, delusions, hallucinations, hypomania and increased or decreased libido.

Neurologic: Incoordination, ataxia, numbness, tingling and paresthesias of the extremities, extrapyramidal symptoms, syncope, changes in EEG patterns.

Anticholinergic: Disturbance of accommodation, paralytic ileus, urinary retention, dilatation of urinary tract.

Allergic: Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus.

Hematologic: Bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia.

Gastrointestinal: Nausea, epigastric distress, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, black tongue.

Endocrine: Testicular swelling and gynecomastia in the male, breast enlargement, galactorrhea and minor menstrual irregularities in the female, elevation and lowering of blood sugar levels, and syndrome of inappropriate ADH (antidiuretic hormone) secretion.

Other: Headache, weight gain or loss, increased perspiration, urinary frequency, mydriasis, jaundice, alopecia, parotid swelling.

Overdosage: Immediately hospitalize patient suspected of having taken an overdose. Treatment is symptomatic and supportive. I.V. administration of 1 to 3 mg physostigmine salicylate has been reported to reverse the symptoms of amitriptyline poisoning. See complete product information for manifestation and treatment.

Dosage: Individualize according to symptom severity and patient response. Reduce to smallest effective dosage when satisfactory response is obtained. Larger portion of daily dose may be taken at bedtime. Single *h.s.* dose may suffice for some patients. Lower dosages are recommended for the elderly.

Limbitrol 10-25, initial dosage of three or four tablets daily in divided doses, increased up to six tablets or decreased to two tablets daily as required. Limbitrol 5-12.5, initial dosage of three or four tablets daily in divided doses, for patients who do not tolerate higher doses.

How Supplied: White, film-coated tablets, each containing 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt) and blue, film-coated tablets, each containing 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt)—bottles of 100 and 500; Tel-E-Dose® packages of 100; Prescription Paks of 50.

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This space contributed as a public service

EDITORIAL

Paradoxical Times

Alfred L. Ferguson, M.D.

FEELINGS are running high, adversely it should be added, in regards to the Diagnosis Related Grouping (DRG) method for Medicare reimbursement to hospitals. One county society wrote congressmen insisting this payment mode was morally and economically wrong and should be repealed for the sake of free enterprise and as a strike against socialism. One hospital administrator copied to me a paper penned by his chief of staff for local physician dispersement addressing DRGs. The paper described October 1, 1983 as an historical date to remember as the day health care delivery became headed "down the tube."

These complaints seem legitimate enough. There appears a paradox amid all the smoke, though. While hospital administrators lament DRGs, there appeared, in the December 19, 1983 issue of *The Internist's Intercom* (Vol. 7:12), a report of . . . "recent audit of 331 hospital bills in 40 states revealed that 93% of the bills contained errors . . . 77% were errors of charges that could not be substantiated. . . . In contrast, 15% of the bills omitted charges for services rendered." Even so . . . "the errors found resulted in an average net decrease per bill of $673." The implication here is phenomenal when extrapolated to all of the hospital discharges across the nation. Assuming the *Intercom's* report is representative of most hospitals and assuming that there were ten million admissions and discharges in the USA in one year, the overbill would amount to five billion one hundred eighty-two million dollars. Regional differences and hospital sizes should be considered, however. Large urban hospitals may be more prone to overbill than small rural ones, or vice versa. Assuming that the *Intercom's* report is accurate, ponder the questions this generates. One is "Why have not the hospitals and the doctors already addressed this issue?" There have been many complaints for years about inefficient billing problems with hospitals. Most people who complain about this problem argue that there is no need to hassle with the problem since "It is so complicated I don't know where to start; and, when you do complain, the billing personnel give you such a rough time and have things so messed up it just isn't worth it. Besides, insurance will cover most of it anyway!"

Some have reported that waste and employees' pilferage in hospitals is astronomical, and no reasonable effort is exerted by the administrations to alter the situation.

Physicians pose an even greater paradox. Twenty years ago hate-government thoughts and frothing at the mouth were typical signs and symptoms endemic to physician gatherings where "socialized medicine" was the topic. Comments were heated and sounded like this: "I have always taken care of the poor, old or not, whether they could pay or not!" Another one was: "I'd as soon die or quit my practice before the government ever pays me one dime!" True enough, there have been many to quit practice and many now work for large companies or the government full time. A few went fishing early. The rest are still in there plugging away with comments now like this: "Those SOBs are still not paying me what I bill!"

The public is also a paradoxical group. Let Mr. and Mrs. John Q. Doe approach the market place and strike a bargain. It seems they have no problem settling for a smaller house or a smaller car when their budget doesn't allow the larger ones. They settle for double knit and an occasional meal out rather than high fashion and gourmet cooking. But, when it comes to medical care, they expect top of the line, comfortable, modern, expert, high-class care delivered flawlessly and fast by a wise, handsome, likable, fatherly physician assisted by a pretty, patient, capable, and loving nurse. For free! No less! "It is my right."

Then, there are the Feds; or there is the Feds. (I have never known which was correct.) They live, breathe, and generate paradox. We must give them one point, though; they never did *say* that they would cover any medical bill one hundred percent. Their sin is they imply it. They allow the press, other news media, and politicians to carry the message uninterrupted and uncorrected to the public that they will "bear the load all the way." They like to think of medical care as a truckload of goods stacked by the numbers, delivered by the pound and consumed by the ounce. Furthermore, they want the services of an all night affair in a king's harem for the price of a one-hour stand in a Hill Street "Ho House."

The federal reimbursement formulas are from outer space. No one understands them. They are disequilibrated rat-a-tat-tat, the 80% of the allowable and the allowable is less than 50% of the unrealistic. The think-tank groups who come up with these formulas designed to bewilder and frustrate do so with methodical madness. Their actions are a mockery of truth from the outset. Such behavior is unforgivable.

It seems no one thinks too clearly nowadays. No one will tell the truth. What is worse, no one knows what the truth is any more. (Of course, given time, the Feds will define it.) Why do not the hospitals admit they are wasteful and they overbill? Why do not the public and the Feds realize that "there ain't no such thing as a free lunch"? Quality medicine costs now and will cost forever. (One question comes to mind when the subject of "quality medical care" is raised. Why don't the Feds offer us *quality government*?)

Why do many doctors fail so often to value their true worth and bill accordingly? Why don't we admit we fail

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From 6 Doctors Park, Greenville 27834.

frequently to be totally truthful, kind, considerate, and respectful of patients and their families? Why do we not explain things to our patients so that they can understand? Why do we not admit to them when our judgment was poor? Why are we rude sometimes just to cover up our own weaknesses and frailties? And most of all, why do we not admit that we never did take care of *all* of the poor, old or not, for free — just some of them!? Remember, neither has the lawyer defended, the preacher ministered, the grocer fed, the retailer clothed, the teacher taught, nor the realtor housed *all* of the poor, old or not, either! This just goes to show us that the sick, the illegal, the sinner, the hungry, the threadbare, the ignorant, and the homeless ye will have with you always.

Despite any thinking to the contrary, we physicians *do* owe our patients a lot, whether we like it or not. We owe them kindness, fairness, explanations, expert care, and "the time of day." Most of all, we owe them and ourselves the truth. We have no right to do otherwise. It is our heritage; if the rest of them do not follow suit that is their problem, not ours.

Advice to Authors

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Medical articles, editorials, patient oriented articles, letters to the editor and all other text submitted for publication must be double-spaced throughout, including references, legends, and all other elements. The material should be typed on one side of the paper with 1¼ inch margins all around. Do not use all-caps or a script typeface. Submit one original and one copy.

The author is responsible for the accuracy of all statements and references. Acronyms and other abbreviations should be kept to a minimum; unless an acronym is widely known and used by all specialties, it should be fully explained in the text. Refer to pharmaceutical products by their generic names; brand names may follow in parentheses..Units of measure should appear in the metric system. References, typed in double-space, should be listed in the order of their citation in the text, not alphabetically. They should follow the style used in articles in the *Journal*.

Illustrations should be black and white glossy prints, with legends typed in double-space on a separate sheet of paper. The *North Carolina Medical Journal* has no budget for printing in color; any author who wishes to publish a four-color figure may negotiate to pay for the costs.

Attach to the two copies of the manuscript a covering letter giving the address and telephone number of the person who will correspond about it and address the completed communication to the Editor, Box 3910, Duke University Medical Center, Durham, NC 27710.

All manuscripts are subject to editorial changes. If extensive revision is necessary, the author will receive a draft of the edited article for approval before publication.

Authors interested in more effective writing may find *The Elements of Style* by Strunk and White and *How to Write and Publish a Scientific Paper* by Day helpful.

Extracted, with permission, from Virginia Medical, with thanks.

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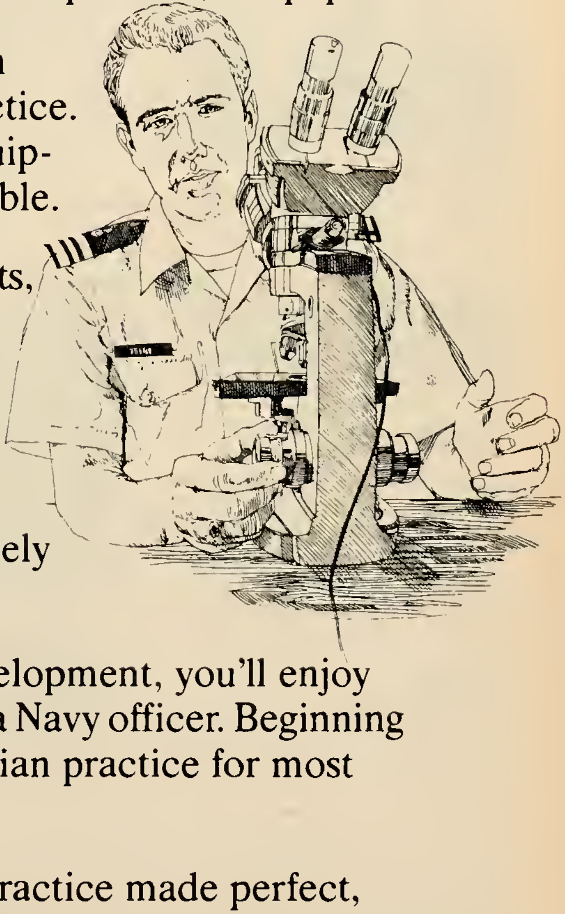

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JOURNAL NEWS

Your Journal's Printer

Ovid H. Bell

NOW that we're into the second year of printing your *North Carolina Medical Journal*, it's high time we introduce ourselves. Perhaps some of you have wondered where Fulton, Missouri, might be, what The Ovid Bell Press, Inc., is and how it came to print your journal. At Dr. Stead's kind invitation, I will try to tell you about all three.

Fulton is a town of not quite 15,000 located 110 miles west of St. Louis and 15 miles north of the Missouri River, the county seat of Callaway County (sometimes referred to as the capital of the Kingdom of Callaway, as a result of a Civil War episode in which sovereignty was supposedly recognized by federal troops). It is the home of two state institutions, two colleges (William Woods College, for women, and Westminster College, originally for men but coeducational since 1979), and several small but nationally known industries. It is perhaps best known for the distinguished leaders who have spoken here at various times: Jefferson Davis (in 1875 to a Confederate veterans' reunion), Winston Churchill, three U. S. Presidents (Truman, Ford, Reagan) and other world figures. The town is near the center of an area often referred to as "Little Dixie" because its original settlers came from Virginia, Kentucky and the Carolinas. The Bells were not among those first settlers, but my widowed great-grandmother, Permelia Gilbert Bell, arrived by river boat in 1855 with three teen-aged sons and five slaves. The Civil War came just a few years after that to find Missouri divided as a border state. This area was steadfast in its support of the Confederacy, and its southern attitudes, if not its accents, continue.

But how did The Ovid Bell Press, Inc., take root and grow on the Missouri prairie, near the foothills of the Ozark Mountains?

The business was begun in 1901 by my father, Ovid Bell, when he acquired a foundering weekly newspaper, which he made into a daily within a few years. A natural part of any county-seat newspaper was its job printing department, and somehow he decided to expand that into larger equipment and get into magazine and book printing. By 1926 he found two things: that the newspaper and the magazine and book printing businesses were not compatible, and that a town of 6000 could not support two daily papers. So he sold his newspaper to its rival and, on January 1, 1927, founded The Ovid Bell Press, to engage in magazine and book printing. The business was incorporated in 1936 as part of the financing program for a new building. Incidentally, I still recall his visiting me that spring (a freshman at Davidson College in your state) to learn my career plans before going ahead, and I've never regretted my commitment to the business.

The business has grown steadily, and the 1936 building has been expanded, with a building addition completed in May of this year, to five times its original size. For many years we were letterpress printers, working with engraved plates and type from Linotype machines, but we have kept abreast of the trend in our industry and converted to offset printing — and we have moved consistently to maintain the highest possible "state of the art" in sheet-fed offset printing.

I can honestly say that I "grew up" in the printing business, taking the helm, at my father's death in 1953, as the company president. I was joined eleven years ago by my son John, now a vice president, and four years ago by my daughter Jane (Ackerman). It's a family business, and I cannot deny the fond hope that my two five-year-old grandsons (and perhaps my two granddaughters as well) will someday be printers here.

While I'll take some credit for the leadership given a growing business, the real key to our success over the years is the kind of people we have in our organization. Some of the "young fellows" who worked with me when I assumed the presidency thirty years ago can now boast 25-40 years' service here. Almost all are local people who have learned the printing craft in our plant, but the few "outsiders" who have joined us provide an important leavening ingredient. It's a group anybody could be proud of, for all have caught the spirit of the company, to give our customers the best we can of both craftsmanship and service.

There is a strange coincidence. The organization today consists of 81 people, from the president's office to those who clean and carry out the waste, and we are handling 82 different publications, plus the book and incidental printing we do for our regular customers. Only a few years ago 55 people were doing 35 publications; automation, faster presses, computerization — and better utilization of manpower — make the difference. Still, craftsmanship is the watchword.

Whether it's one of the Bells, vice presidents Bob Epperson or Raymond Miller, Dan Grubb (a transplanted Marylander who handles your account), one of our service representatives or foremen, clerical or production workers, each is a member of a team dedicated to serving our customers.

With a western sales office in the San Francisco area, we are serving customers from coast to coast. We print a variety of scientific and professional journals, trade magazines, fraternity and other association publications. The *North Carolina Medical Journal* is one of ten state medical journals we print, in addition to five medical specialty journals for the C. V. Mosby Company of St. Louis, *The Pharos* of Alpha Omega Alpha and *Federation Bulletin* for the Federation of State Medical Examining Boards.

From 1201-1205 Bluff Street, Fulton, MO 65251.

This process camera provides film negatives for all materials to be printed.

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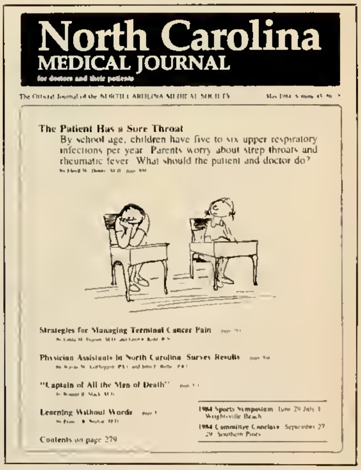

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for doctors and their patients

The Official Journal of the NORTH CAROLINA MEDICAL SOCIETY

The Patient Has a Sore Throat
By school age, children have five to six upper respiratory infections per year. Parents worry about strep throats and rheumatic fever. What should the patient and doctor do?

Strategies for Managing Terminal Cancer Pain

Physician Assistants in North Carolina: Survey Results

"Captain of All the Men of Death"

Learning Without Words

1984 Sports Symposium June 29-July 1 Wrightsville Beach

1984 Committee Conclave September 27-29 Southern Pines

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The finished product.

Our state medical journal business began logically enough with *Missouri Medicine*, and the Missouri State Medical Association is one of three customers whom we have served more than 50 years. The Iowa and Kansas journals came in the early 1950s, followed by Mississippi, Georgia, Alabama, Louisiana, Rhode Island, North Carolina, and South Dakota. Our experience with medical texts and illustrations has been enhanced by book work for Charles C Thomas, Publisher and Year Book Medical Publishers. Our interest in overall publishing, advertising and mailing requirements, along with our long-time working relationship with the State Medical Journal Advertising Bureau (of which your journal is a charter member), has made it possible for us to offer an attractive package to each of the state medical societies we serve.

In its 57th year, The Ovid Bell Press looks to the future with plans for continuing growth and keeping pace with the rapidly changing technology of our industry — all to serve our customers better. We hope that North Carolina doctors will for many years to come be reading a journal we have printed for them in Fulton, Missouri.

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Two Especially Noteworthy CMEs

FALL TOUR OF SPAIN

The North Carolina Medical Society invites its members, their spouses, and their guests to join a Fall tour of Spain.

The nine-day (October 13-21) tour of Madrid and the Andalusia region is specially designed to blend the professional and tax advantages of continuing medical education with the excitement and fun of vacation travel.

The CME program, which combines lectures by the faculty of the Autonomous University of Madrid with visits to Spanish hospitals and clinics, has been reviewed and is acceptable for 20 hours prescribed credit by the American Academy of Family Physicians.

The Society-endorsed trip was planned in association with Mr. Jose Infante, President of J. M. Sales, Inc., and the American Leadership Study Groups, an educational travel organization based in Worcester, Massachusetts. Born in Cuba, Mr. Infante is an American citizen and a longtime Raleigh resident who has worked for the N.C. Department of Public Instruction. He will lead the tour.

The trip includes: a round-trip flight via scheduled airline

from Raleigh-Durham (RDU) or Charlotte airport to Madrid; seven nights' accommodations and breakfasts in a deluxe, five-star hotel in central Madrid; a gala dinner with Spanish physicians and their spouses; airport transfer, baggage handling, and travel insurance; a fashion show and a demonstration of Spanish culinary art; half-day sightseeing in Madrid and its environs with professional guides; a hospitality desk with local tour information and suggestions; and welcome and farewell cocktail parties.

Trip costs are $1,495 per person from RDU or $1,569 per person from Charlotte. The $300 seminar fee and the fees for optional excursions are extra.

All Society members should have already received a brochure and a registration form for the trip.

Society members, spouses, and their friends are urged to complete the accompanying registration form and join this custom-tailored tour of Spain.

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ETHICS CONFERENCE AT GRAYLYN

You are cordially invited to attend "Medical Ethics In An Age of Science" on August 10-11 at the Graylyn Conference Center in Winston-Salem. The North Carolina Medical Society and Bowman Gray School of Medicine of Wake Forest University are co-sponsoring this conference, which will brief state leaders in medicine, business, religion, and education on the ethical challenges presented by new medical technology, reduced funding for medical care, and changing values.

The conference is a project of the Society's Committee on Ethics & Religion, formerly chaired by Gloria F. Graham, M.D., of Wilson. Richard Janeway, M.D., Dean of Bowman Gray School of Medicine, will serve as the conference moderator.

The roster of distinguished speakers includes:

Dr. Thomas K. Hearn, President, Wake Forest University; Edmund D. Pellegrino, M.D., John Carroll Professor of Medicine & Medical Humanities, Georgetown University Medical Center; Dr. J. Stanley McQuade, Lynch Professor of Law, Campbell University; Mr. Kevin Murphy, Vice President, First Union National Bank; Mr. Calvin Michaels, Director of Personnel, Burlington Industries; Mr. Don Patterson, Program Administrator, IBM, Research Triangle Park; and Stuart Bondurant, M.D., Dean, UNC School of Medicine, Chapel Hill.

Graylyn Conference Center was the home of industrialist Bowman Gray, and is the second-largest private home ever built in North Carolina. It is a national historic landmark, now operated as a conference center by Wake Forest University. Graylyn is a splendid and unique facility located on a 55-acre estate.

Conference check-in begins at 5 p.m. on Friday, August 10, followed by a cocktail reception, dinner, and the dinner speaker. The conference concludes after lunch on Saturday, August 11. A complete hourly schedule will be mailed to registrants.

Accommodation and conference fees include the cost of three meals and the reception for attendees. Conference spaces are limited. You are urged to complete and mail the registration slip below as soon as possible. Make checks payable to the North Carolina Medical Society.

Please register me for:
Medical Ethics In An Age of Science — August 10-11, 1984
Graylyn Conference Center
Winston-Salem, N.C.

______________________ name(s)
______________________ title — organization
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room rate $125 (single) or $175 (double) __________
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George Richardson
P.O. Box 2113
Winston-Salem, NC 27102

Please provide me complete information on the Disability Income Protection Plan available to members of the North Carolina Medical Society who are under age 55.

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Bulletin Board

Continuing Medical Education

Please note: 1. The Continuing Medical Education Programs at Bowman Gray, Duke, East Carolina and UNC Schools of Medicine, Dorothea Dix, and Burroughs Wellcome Company are accredited by the American Medical Association. Therefore CME programs sponsored or cosponsored by these schools automatically qualify for AMA Category I credit toward the AMA's Physician Recognition Award, and for North Carolina Medical Society Category A credit. Where AAFP credit has been obtained, this also is indicated.

IN STATE

July 18
Hospital Nutrition Update
Place: Sanford
Credit: 2 hours
Info: R. S. Cline, M.D., Central Carolina Hospital, 1135 Carthage St., Sanford 27330, 919/774-4100, ext 394

July 19-21
Sixth Annual Mountain Meeting
Place: Asheville
Credit: 12 hours, Category 1 AMA
Fee: $150
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103

July 30-August 3
Diagnostic Imaging
Place: Atlantic Beach
Fee: $425
Credit: 25 hours
Info: J. D. Wright, Box 3808, Duke Hospital, Durham 27710. 919/681-2711

August 4
Geriatric Education Day
Place: Raleigh
Credit: 4 hours
Info: NCAFP 919/781-6457

August 7
Malpractice Awareness — STAT
Place: Greensboro
Info: Wayne Parker. 919/828-9334

August 14
Malpractice Awareness — STAT
Place: Charlotte
Info: Wayne Parker. 919/828-9334

August 15
Electrolytes/Arterial Blood Gases/Fluid Balance
Place: Sanford
Credit: 2 hours
Info: R. S. Cline, M.D., Central Carolina Hospital, 1135 Carthage St, Sanford 27330. 919/774-4100, ext 394

August 21
Malpractice Awareness — STAT
Place: Goldsboro
Info: Wayne Parker. 919/828-9334

August 24, 26
Summer Urology Conference
Place: Winston-Salem
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103

September 9-12
Basic Clinical Teaching Skills
Place: Rougemont
Credit: 20 hours Category I and AAFP
Info: Katharine Munning, 407 Crutchfield Street, Durham 27705. 919/471-2571.

September 9-13
Clinical Skills Workshops and Review
Place: Winston-Salem
Credit: 31 hours Category I
Fee: $395
Info: Elizabeth B. Philp, Department of Family Medicine, Bowman Gray School of Medicine, Winston-Salem 27103.

September 11
New Developments in Clinical Medicine
Place: Fayetteville
Credit: 7 hours AAFP
Info: Mary Henley. 919/323-1152.

September 21
Sixth Annual Health Law Forum
Place: Greenville
Info: Mary Valand, Box 7224, ECU School of Medicine, Greenville 27834. 919/758-5200.

September 21-22
New Advances in the Treatment of Sickle Cell Disease
Place: Wrightsville Beach
Credit: 8 hours Category I
Info: Cindi Easterling, Box 3108, DUMC, Durham 27710. 919/684-6878.

September 28-29
Adolescent Health Issues: Challenges for the 1980s
Place: Durham
Credit: 9 hours Category I
Info: Cindi Easterling, Box 3108, DUMC, Durham 27710. 919/684-6878.

OUT OF STATE

July 26-28
6th Annual Pediatrics Primary Care Conference
Place: Virginia Beach, VA
Credit: 12 hours
Fee: $275
Info: S. Rosner, Box 48 MCV Station, Richmond, VA 23298. 804/786-0494

July 30-August 3
12th Annual Beach Workshop
Place: Myrtle Beach, SC
Credit: 20 hours AMA Category I
Fee: $225
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103

August 12-17
Symposium on the Surgical Treatment of Cancer
Place: Orlando, FL
Credit: 20 hours Category I AMA
Info: C. Easterling, Box 3108 Duke Hospital, Durham 27710. 919/684-6878

September 6-8
Doppler Echocardiography
Place: Charleston, SC
Credit: 24 hours Category I
Fee: $350
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/748-4450.

September 13-15
Advanced Applied Ultrasound in Obstetrics
Place: Myrtle Beach, SC
Credit: 12 hours Category I
Fee: $350
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/748-4505.

First in a series of reports from your colleagues about Medical Mutual Insurance Co. of North Carolina

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James E. Davis, M.D.
Surgeon, Durham, NC, and
President, Medical Mutual Insurance
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Medical Mutual Insurance Company of North Carolina and Medical Insurance Agency, 222 N. Person Street, P.O. Box 27444, Raleigh, N.C. 27611. Phones: Raleigh 828-9334 or Statewide 1-800-662-7917

Letters to the Editor

Cephalosporin Allergy

To the Editor:

This letter is in reference to your article, The Patient Has a Sore Throat. What Should the Patient and Doctor Do? (NCMJ 1984;45:309-312, May). In the article it was said, "For the patient who is allergic to penicillin, oral erythromycin is the antibiotic of choice. For the rare patient who cannot tolerate either of these two drugs, an oral cephalosporin or clindamycin can be used."

It is important to note, and many physicians may not know, that 25 to 50 percent of the patients allergic to penicillin may be sensitive to cephalosporin.

Claude A. Frazier, M.D.
Doctors Park
Asheville 28801

Strategies for Pain Management in Terminal Cancer

To the Editor:

Congratulations to you and your staff on publishing an excellent article (NCMJ 1984;45:283-290, May). Dr. Linda Frazier and Errol Kohl have written one of the most accurate an significant articles on the subject of pain and the terminal patient. Their assessment of an actual problem with its solution indicates deep humanity and compassion for the subject.

The case representation is a perfect example of the bind the patient is caught in when priorities are not uniformly set to meet needs. I truly hope that physicians not only read this article, but absorb the sound advice. More importantly, let us hope they use the recommended strategies in their medical practices.

Thank you for the support this article has given me and for the help it will bring to the terminal patient.

Eileen Bardsley, R.T.
1310 Crestview Drive
Shelby 28150

Words of Praise for Words of Wisdom

To the Editor:

John Graham's editorial (NCMJ 1984;45:325-326, May) is a jewel obviously formed by the crystallization of vast experience over substantial time in an atmosphere of institutional heat and pressure. I offer two observations.

Not once did Dr. Graham use the word "power."

Dr. Graham's admonitions, I fear, can be learned but not taught.

David L. Silber, M.D.
Moses H.Cone Memorial Hospital
Greensboro 27401

In Opposition to Moonlighting

To the Editor:

The discussion of moonlighting by family medicine residents (NCMJ 1984;45:247-248, April) approaches the subject only from the perspective of its impact on medical education. Patient care may be by far the more important issue.

Residents moonlight not to increase outpatient encounters, but instead to earn extra income. They perform as "attending physicians" and accept wages determined by the laws of supply and demand. Moonlighting usually occurs in hospital emergency departments and private primary care clinics. Patients presenting to hospital emergency departments deserve care from physicians competent to practice the specialty of emergency medicine. Residents could hardly moonlight as radiologists, gynecologists, neurologists, or orthopaedists . . . why, then, should we condone the practice of emergency medicine by physicians still in training?

Emergency medicine specialists possess skills most family medicine residents do not have. True emergencies often cannot wait for an on-call specialist to come from home to the hospital.

If family medicine residents require additional outpatient encounters, as Kelly and Sharp suggest, these should be well-supervised and preferably under the auspices of their training program.

Dean Dobkin, M.D.
6817 El Greco Court
Pineville 28134

Fentanyl

To the Editor:

This office wishes to call the attention of your readers to information we have received regarding the diversion and abuse of fentanyl related chemicals among some elements of the medical community. Our concerns are particularly directed to personnel assigned to operating rooms where the drug is used as an anesthetic. Reliable sources lead us to believe that fentanyl and/or certain of its analogs have been the cause of diversion, abuse, and death in this state, as well as in other locations throughout the country.

Fentanyl is a synthetic anesthetic currently used in hospitals under the brand names of Innovar or Sublimaze and will produce the classic narcotic effects including euphoria, suppression of body functions and death. An almost limitless number of analogs or variations of fentanyl can be produced with potencies ranging from 80 times that of morphine and up.

This drug also is sold on the streets under the name "China White." Even though its presence among street addicts in North Carolina is nominal at present, we are expecting a substantial increase in overdose emergencies at any time. Our information from the Department of Alcohol and Drug Programs in California is that thirty plus deaths have occurred in that state where the cause of death can be directly identified as one of the fentanyl analogs. Some of the identified street analogs are 3-methyl fentanyl, alpha methyl fentanyl, and para floral fentanyl. Since there is a suspicion that a very substantial portion of all heroin sold in

California may actually be an illicitly manufactured form of fentanyl, there is an added concern for its eventual impact on our state. Fentanyl-like chemicals are *not detectable* by the usual laboratory drug screens. Therefore, it is believed that narcotic overdose deaths may be caused by fentanyl analogs.

Due to the extreme danger related to the misuse and abuse of this drug, I would appreciate being notified when diversion is suspected or when technical assistance is needed in making identification.

Steven L. Hicks, Deputy Director
Alcohol and Drug Abuse Services
325 N. Salisbury Street
Raleigh 27611

We Thought You'd Like to Know

Resolution from Buncombe County at NCMS Annual Meeting, May 1984

WHEREAS, several years ago *The North Carolina Medical Journal* came under extreme criticism for failing to be an effective vehicle for the North Carolina Medical Society; and

WHEREAS, the Buncombe County Medical Society, among others, led the battle to effect improvement or dissolution of *The Journal;* and

WHEREAS, the House of Delegates in 1982 mandated a vigorous attempt to upgrade *The Journal;* and

WHEREAS, since January 1, 1983, under the Editorship of Eugene A. Stead, Jr., M.D., along with a new staff of assistants, *The Journal* has markedly improved in quality, format, interest, and general usefulness; and

WHEREAS, the "Features for Patients" section has been praised warmly by our patients; therefore be it

RESOLVED, that this House of Delegates of 1984 go on record as warmly congratulating the current editor, his staff and the many physicians of the State Society who have worked to improve *The Journal.*

Report of the Ad Hoc Committee to Evaluate the *North Carolina Medical Journal*

We have continued to review the *North Carolina Medical Journal* from 1982 to the present. We have followed the costs of the *Journal* for 1982 and 1983, and have seen the proposed budget for 1984. We have also studied the results of the Tarrance & Associates phone survey and read the Annual Report of the *Journal's* Editorial Board.

The features of the *Journal* that were introduced in 1982 have been maintained. A recent issue contained 15 articles and the "Features for Patients" section. The topics were varied and timely.

The cost of the *Journal* in 1982 was $15.19 per member. The 1983 cost was $14.00 per member. The projected cost for 1984 will be slightly less if membership increases.

The phone survey revealed that 71% of the membership sample read the *Journal* totally or in part; 56% of our membership felt that the *Journal* should be enlarged; 17% of the sample felt that the *Journal* should be discontinued if, for financial reasons, the North Carolina Medical Society needed to consider the future of the *Journal.*

The *North Carolina Medical Journal* was not placed under the Department of Communications as we recommended. We do not feel that the failure to do this has been detrimental either to the *Journal* under the editorship of Dr. E. A. Stead, Jr., or to the efforts of Mr. Tom Bennett, the Communications Director.

Mr. Speaker, members of the House of Delegates, the ad hoc Committee to Evaluate the *North Carolina Medical Journal* reports that the Editorial Board and the Staff have continued the improvements started in 1982 and 1983. We compliment them for doing so without increasing costs. *We recommend that the North Carolina Medical Journal continue to serve our membership in the future as in the past.*

I appreciate the efforts of Dr. Susan Gustke and Dr. Phil Naumoff in the compilation of this report.

William W. Fore, M.D., Chairman
1705 W. Sixth Street
Greenville 27834

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TALWIN® Nx is intended for oral use only Severe, potentially lethal, reactions may result from misuse of TALWIN® Nx by injection either alone or in combination with other substances (See **Drug Abuse and Dependence** section)

Warnings: *Drug Dependence* Can cause physical and psychological dependence (See **Drug Abuse and Dependence**) *Head Injury and Increased Intracranial Pressure* As with other potent analgesics, respiratory depressant effects of the drug may elevate cerebrospinal fluid pressure due to CO_2 retention, these effects may be markedly exaggerated in the presence of head injury, other intracranial lesions, or a preexisting increase in intracranial pressure Can obscure the clinical course of patients with head injuries, in such patients, use with extreme caution and only if deemed essential *Usage with Alcohol* Due to potential for increased CNS depressant effects, alcohol should be used with caution *Patients Receiving Narcotics* Pentazocine is a mild narcotic antagonist Withdrawal symptoms have occurred in patients previously given narcotics, including methadone *Certain Respiratory Conditions* Should be administered with caution in respiratory depression from any cause, severely limited respiratory reserve, severe bronchial asthma and other obstructive respiratory conditions, or cyanosis

Precautions: *CNS Effect* Use cautiously in patients prone to seizures, seizures have occurred though no cause and effect relationship has been established Therapeutic doses have in rare instances, resulted in hallucinations (usually visual), disorientation, and confusion, which cleared spontaneously within a period of hours Such patients should be very closely observed and vital signs checked, if the drug is reinstituted, it should be done with caution since the acute CNS manifestations may recur *Impaired Renal or Hepatic Function* Decreased metabolism of pentazocine in extensive liver disease may predispose to accentuation of side effects, it should be administered with caution in renal or hepatic impairment In long-term use, precautions should be taken to avoid increases in dose by the patient *Biliary Surgery* Some evidence suggests that unlike other narcotics pentazocine causes little or no elevation in biliary tract pressures, the clinical significance of these findings is not yet known *Information for Patients* Since sedation, dizziness, and occasional euphoria have been noted, ambulatory patients should be warned not to operate machinery, drive cars, or unnecessarily expose themselves to hazards May cause physical and psychological dependence taken alone and may have additive CNS depressant properties in combination with alcohol or other CNS depressants *Myocardial Infarction* Use with caution in patients with myocardial infarction who have nausea or vomiting *Drug Interactions Usage with Alcohol* See **Warnings**. *Carcinogenesis, Mutagenesis, Impairment of Fertility* No long-term studies in animals to test for carcinogenesis have been performed *Pregnancy Category C* Should be given to pregnant women only if clearly needed *Labor and Delivery* Use with caution in women delivering premature infants Effect on mother and fetus, duration of labor or delivery, need for forceps delivery or other intervention or resuscitation of newborn, or later growth, development, and functional maturation of the child is unknown *Nursing Mothers* Caution should be exercised when administered to a nursing woman *Pediatric Use* Safety and effectiveness in children below the age of 12 years have not been established

Adverse Reactions: *Cardiovascular* Hypotension, tachycardia, syncope *Respiratory* Rarely, respiratory depression *CNS Acute CNS Manifestations* In rare instances, hallucinations (usually visual), disorientation, and confusion which have cleared spontaneously within a period of hours, may recur if drug is reinstituted *Other CNS Effects* Dizziness, lightheadedness, sedation, euphoria, disturbed dreams, hallucinations, irritability, excitement, tinnitus, tremor *Gastrointestinal*. Nausea vomiting, constipation diarrhea, anorexia, rarely abdominal distress *Allergic* Edema of the face, dermatitis, including pruritus, flushed skin, including plethora *Ophthalmic* Visual blurring and focusing difficulty *Hematologic* Depression of white blood cells (especially granulocytes), which is usually reversible, moderate transient eosinophilia *Other* Headache, chills insomnia, weakness, urinary retention

Drug Abuse and Dependence: *Controlled Substance* TALWIN Nx is a Schedule IV controlled substance

Dependence and withdrawal symptoms have been reported with orally administered pentazocine Patients with a history of drug dependence should be under close supervision Possible abstinence syndromes in newborns after prolonged use of pentazocine during pregnancy have been reported In prescribing for chronic use, the physician should take precautions to avoid increases in dose by the patient Tolerance to the analgesic effect is rarely reported, there is no long-term experience with oral use of TALWIN Nx

The amount of naloxone present (0 5 mg per tablet) has no action when taken orally and will not interfere with the pharmacologic action of pentazocine, however, this amount of naloxone given by injection has profound antagonistic action to narcotic analgesics TALWIN Nx has a lower potential for parenteral misuse than the previous oral pentazocine formulation, but is still subject to patient misuse and abuse by the oral route

Severe, even lethal, consequences may result from misuse of tablets by injection either alone or in combination with other substances, such as pulmonary emboli, vascular occlusion, ulceration and abscesses, and withdrawal symptoms in narcotic dependent individuals

Overdosage: *Treatment* Oxygen intravenous fluids, vasopressors, and other supportive measures should be employed as indicated Assisted or controlled ventilation should also be considered For respiratory depression, parenteral naloxone (Narcan®, available through Endo Laboratories) is a specific and effective antagonist

Please consult full product information before prescribing

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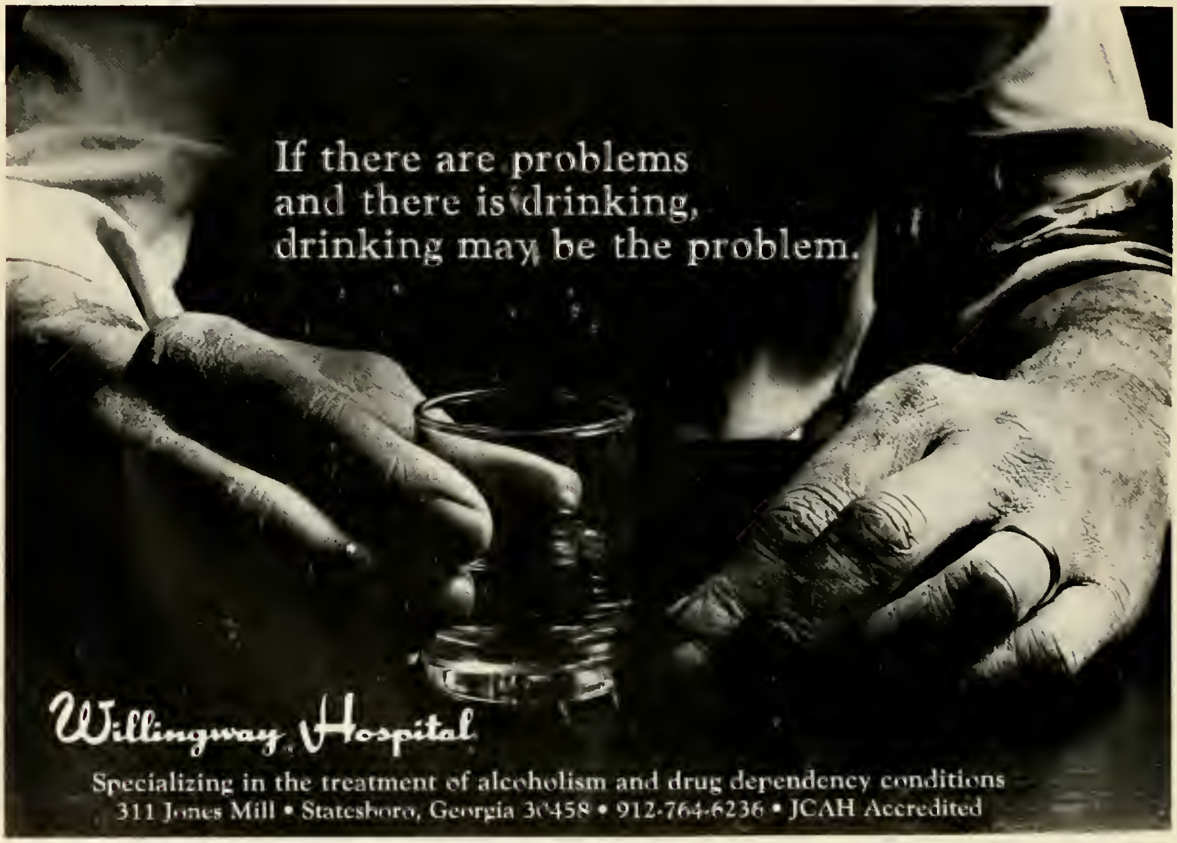

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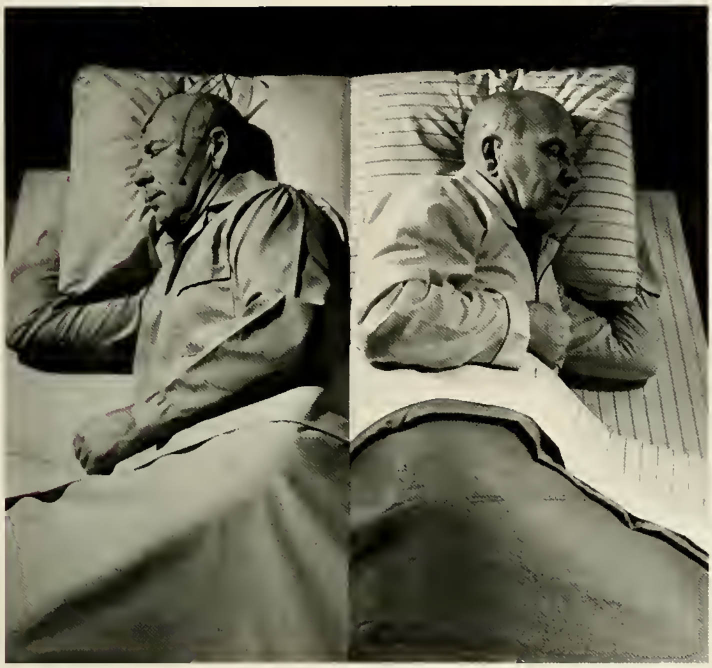

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References: 1. Kales J *et al*: *Clin Pharmacol Ther* *12*:691-697, Jul-Aug 1971. **2.** Kales A *et al*: *Clin Pharmacol Ther 18*:356-363, Sep 1975. **3.** Kales A *et al*: *Clin Pharmacol Ther 19*:576-583, May 1976. **4.** Kales A *et al*: *Clin Pharmacol Ther 32*:781-788, Dec 1982. **5.** Frost JD Jr, DeLucchi MR: *J Am Geriatr Soc 27*:541-546, Dec 1979. **6.** Kales A, Kales JD: *J Clin Pharmacol* 3:140-150, Apr 1983. **7.** Greenblatt DJ, Allen MD, Shader RI: *Clin Pharmacol Ther 21*:355-361, Mar 1977. **8.** Zimmerman AM: *Curr Ther Res 13*:18-22, Jan 1971. **9.** Amrein R *et al*: *Drugs Exp Clin Res* 9(1):85-99, 1983. **10.** Monti JM: *Methods Find Exp Clin Pharmacol* 3:303-326, May 1981. **11.** Greenblatt DJ *et al*: *Sleep* 5(Suppl 1):S18-S27, 1982. **12.** Kales A *et al*: *Pharmacology* 26:121-137, 1983.

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Precautions: In elderly and debilitated patients, it is recommended that the dosage be limited to 15 mg to reduce risk of oversedation, dizziness, confusion and/or ataxia. Consider potential additive effects with other hypnotics or CNS depressants. Employ usual precautions in severely depressed patients, or in those with latent depression or suicidal tendencies, or in those with impaired renal or hepatic function.

Adverse Reactions: Dizziness, drowsiness, lightheadedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported: headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weakness, palpitations, chest pains, body and joint pains and GU complaints. There have also been rare occurrences of leukopenia, granulocytopenia, sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, total and direct bilirubins, and alkaline phosphatase; and paradoxical reactions, e.g., excitement, stimulation and hyperactivity.

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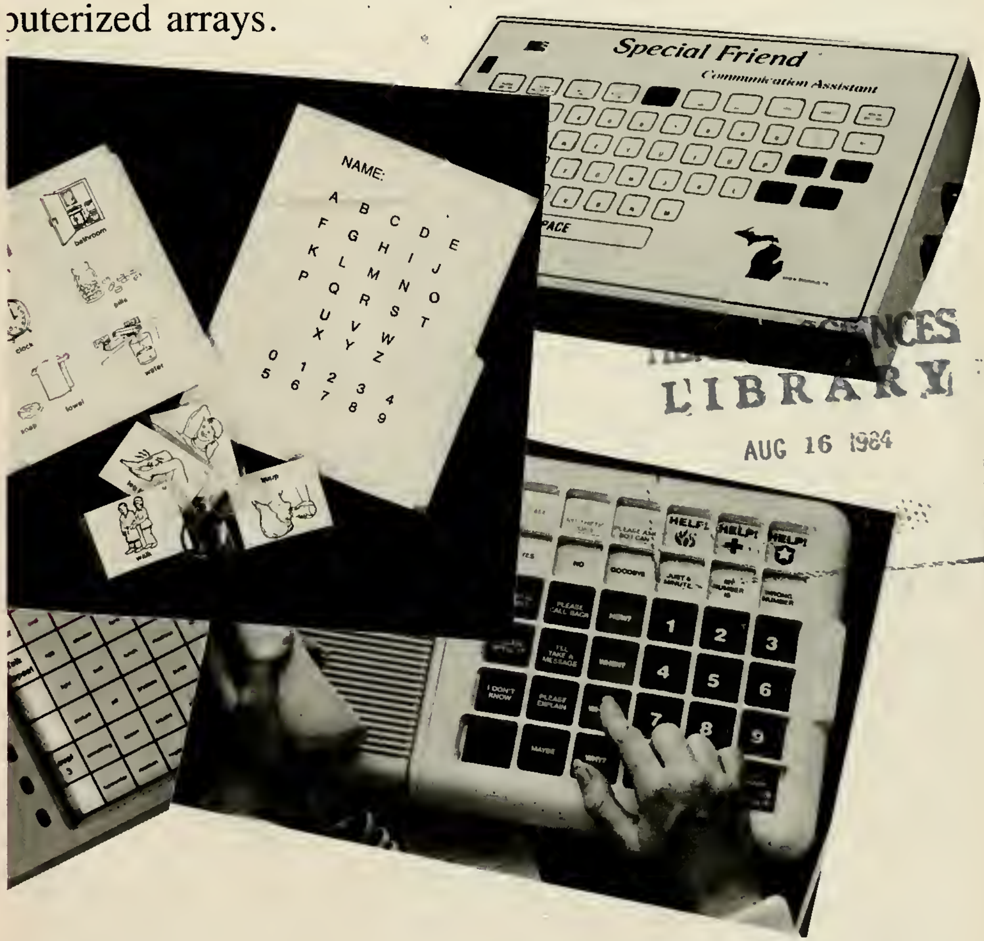

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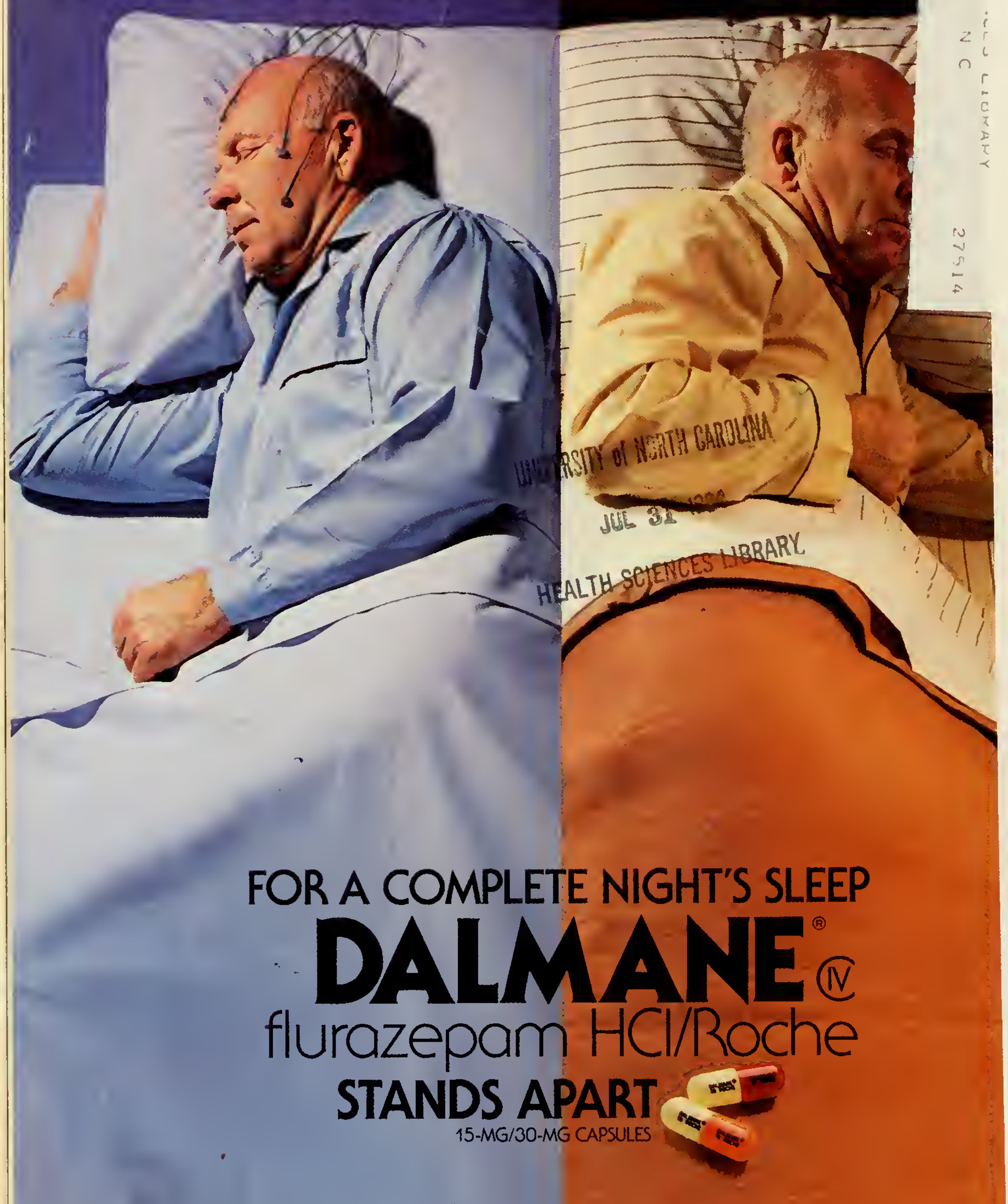

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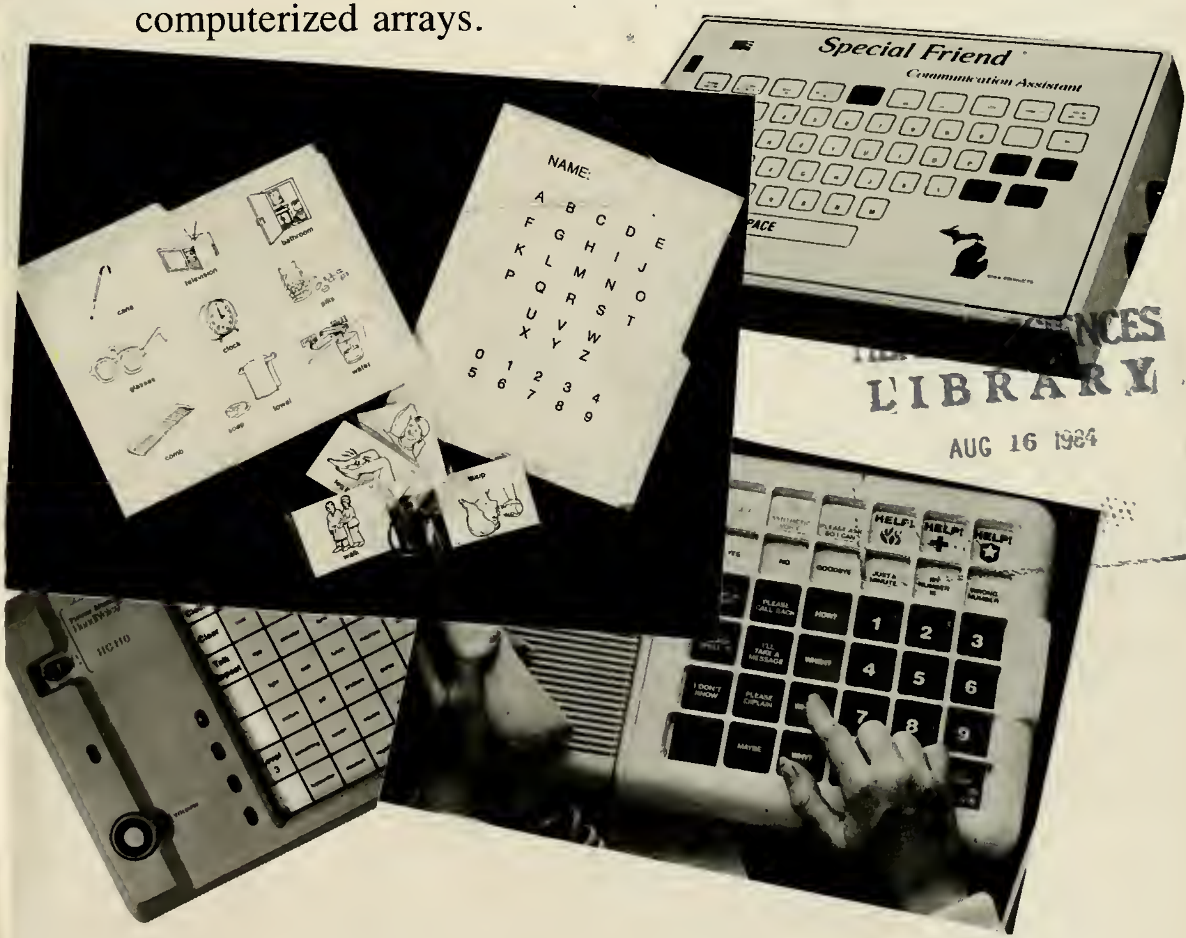

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Published Monthly as the Official Organ of The North Carolina Medical Society (ISSN-0029-2559)

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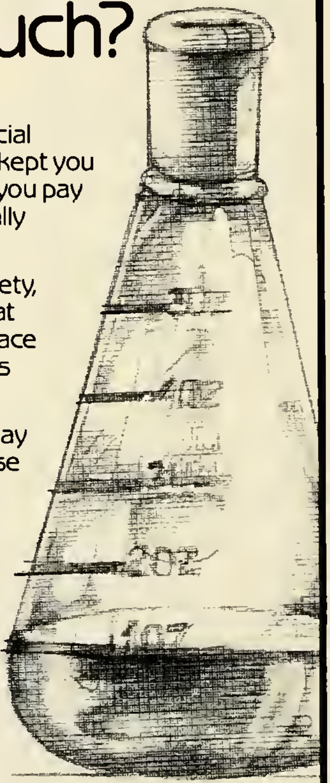

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Sports Medicine Kit

James D. Hundley, M.D.

MY first experience as a sideline physician was at a high school football game. A fellow orthopaedic surgeon was a team physician and accepted the responsibility for covering all home and most out-of-town games for a local school. For the home game that Friday he had to be away.

Having completed a residency in orthopaedic surgery and two years in the armed services, I felt comfortable in the anticipation of management of whatever injuries may occur. I took the little black bag he handed me and went to the game.

My first glance into the bag was fortunately the biggest surprise of the evening. It contained a stethoscope, a percussion hammer, a tuning fork, some tongue blades, a sphygmomanometer, and a combination otoscope-ophthalmoscope. I had nothing with which to TREAT anything. Not only would I have been at the mercy of the student trainer for injury equipment but, had a spectator had an emergency medical problem, I would have been unable to do much more than ride with him in an ambulance to an emergency room. Needless to say, during that evening I worried about more important outcomes than the game score.

Soon after that game an article by Ben R. Mayne, M.D., was published in *The Physician and Sports Medicine*.[1] In that article Dr. Mayne discussed the need for a well-equipped sports medicine bag, provided a list of essential equipment, and suggested using a large fishing-tackle box instead of a black bag (figure 1). That list was slightly revised after consultation with other orthopaedic surgeons, cardiologists, and anesthesiologists. It was then submitted to the members of the North Carolina Medical Society's Committee on the Medical Aspects of Sports and revised again. The list has been revised annually since 1976 using our own experience and that of colleagues in otolaryngology, neurosurgery, and general surgery, as well as those mentioned earlier. It has also been compared with the list in an article by James M. Glick, M.D. published in *Orthopaedic Clinics of North America*.[2]

Consideration of the following points should precede the listing of the contents of the kit:

1. No kit of manageable size and shape can contain everything one may need in an emergency situation. Each physician must decide for himself what the essential items are.

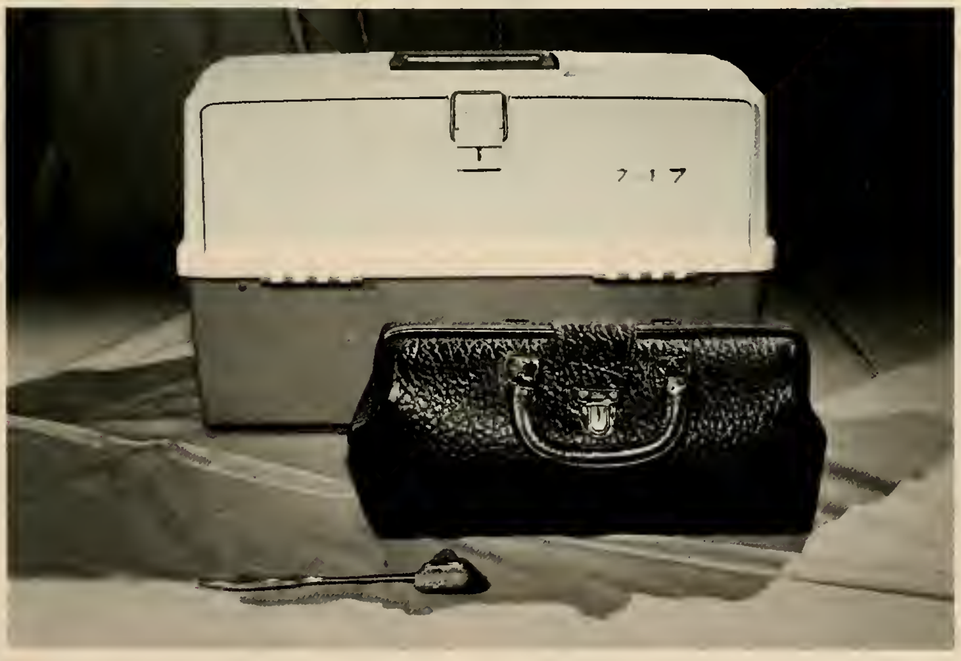

Figure 1.

From the Wilmington Orthopedic Group, 2001 S. 17th Street, Wilmington 28401-6693.

The author is grateful to the New Hanover-Pender Medical Society and the Committee on the Medical Aspects of Sports of the North Carolina Medical Society for their help in developing and refining the sports medicine kit.

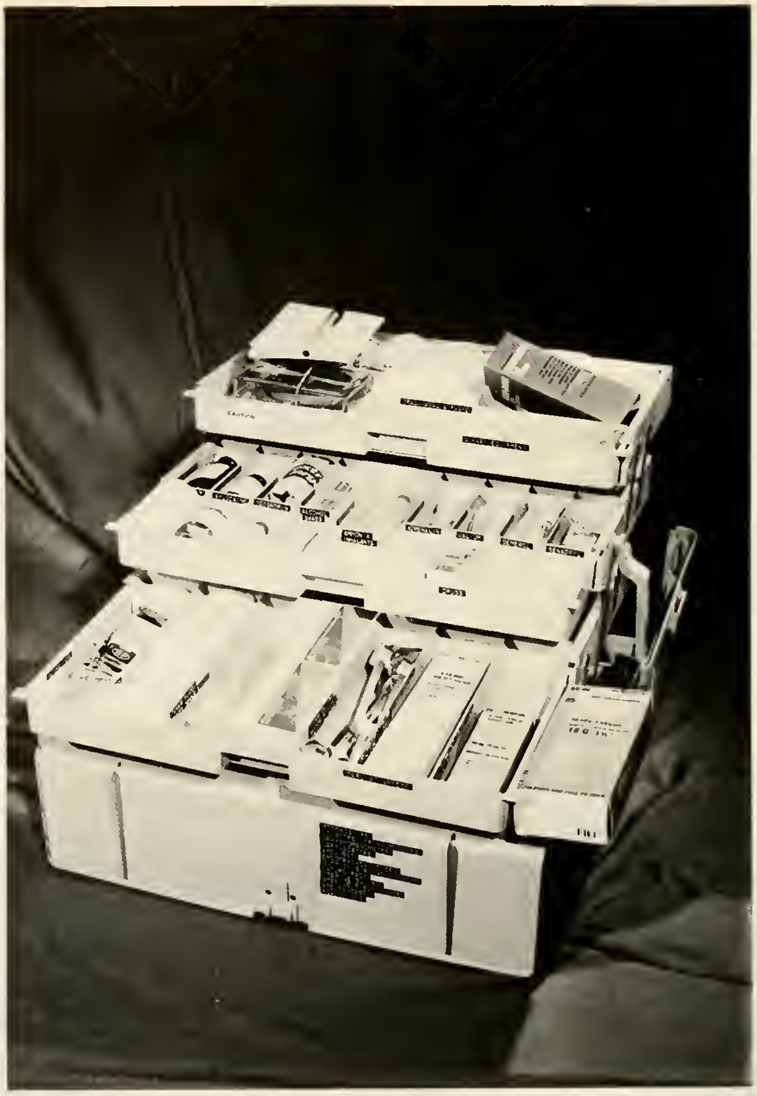

Figure 2.

The Physician's Sports Medicine Kit

I. Diagnostic Equipment
- 1 Stethoscope
- 1 Otoscope/Ophthalmoscope
- 10 Tongue Blades
- 1 Percussion Hammer
- 1 Sphygmomanometer

II. Emergency Airway Equipment
- 1 Padded Tongue Blade
- 1 Bite Screw
- 2 Oral Airways (1 medium and 1 large)
- 2 Nasal Airways (sizes 26 and 34)
- 3 Endotracheal Tubes with Inflatable Cuff (sizes 6, 7, and 8mm. I.D.)
- Stylet for Endotracheal Tubes
- 2 10cc. Syringes to inflate cuffs
- 1 Laryngoscope with 2 Blades (1 straight and 1 curved)
- 1 Ambu Bag with 2 masks (1 large and 1 small) and Attachments for Endotracheal Tube
- 1 50cc. Syringe and Tubing for Suction
- 1 Towel Clip

III. Medicines and Parenteral Access Equipment
- 2 Ammonia Inhalants
- 2 Vials Epinephrine 1:1000
- 1 10cc. Abboject Syringe with 1:10,000 Epinephrine and Cardiac Needle
- 1 5ml. Abboject Syringe with 2% Lidocaine Hydrochloride for Cardiac Arrythmias
- 1 10ml. Vial of Tensilon
- 1 10mg. Vial Injectable Valium
- 2 20mg. Vials Benadryl
- 2 50mg. Vials Demerol
- 2 50cc. Ampules of Sodium Bicarbonate
- 1 50cc. Ampule of D_{50}W
- 1 50mg. Vial Decadron
- 1 50mg. Vial Atropine
- 1 Isuprel Mistometer
- 2 5cc. Syringes
- 3 3cc. Syringes
- 2 18g. Needles
- 3 22g. Needles
- 3 25g. Needles
- 2 #14 Intracaths for Subclavian Venipuncture
- 4 Alcohol Swabs

IV. Eye Materials
- 4 Fluor-I-Strips
- 1 Irrigation Container of Ophthalmic Irrigation Solution

V. Suturing and Wound Equipment
- 1 Suture Set to contain:
  - 1 Needle Holder
  - 2 Hemostats — small
  - 1 Hemostat — large
  - 1 Forceps
  - 1 Suture Scissor
  - 1 Scalpel Handle and 2 Blades
  - 1 Allis Clamp
- 3 Packs of Suture
- 2 1oz. Packs of Betadine Solution
- 1 50ml. Vial of 1% Xylocaine
- 1 Tube Neosporin-G Cream
- 2 Pairs Sterile Gloves
- 1 Disposable Sterile Field
- 1 Disposable Fenestrated Drape

VI. Bandages and Splints
- 20 Band-Aids — standard
- 5 Band-Aids — large
- 5 4x4 Gauze Sponges
- 5 2x2 Gauze Sponges
- 2 2in. Rolls Kling Gauze
- 1 4in. Elastic Bandage
- 2 3in. Elastic Bandages
- 3 Rolls 4in. Plaster
- 3 Rolls 3in. Cast Padding
- 2 Foam Covered Aluminum Finger Splints
- 2 Triangular Slings
- 2 1in. Rolls Adhesive Tape
- 1 Bandage Scissor

Equipment Schools Should Have (not included in the sports medicine kit)
- 1 Bolt Cutter — double action
- 1 Stretcher
- 1 Backboard
- 2 Blankets
- 4 Sandbags
- 2 Pair Crutches — adjustable lengths
- 3 Slings
- 4 Splints — 2 upper extremity and 2 lower extremity
- 36 Rubberized Elastic Bandages:
  - 12 3 inch
  - 12 4 inch
  - 12 6 inch
- Ice — with small plastic bags for containers

2. Athletes are not the only potential patients at athletic events. Should any onlooker suffer any significant medical problem, the team physician is the most visible and possibly the only equipped doctor available. He should expect to be the first called.

3. No individual physician should be expected to treat every conceivable emergency nor should he necessarily know all possible applications of everything in his kit. At many games, other physicians will be in attendance and they may be able to help out. But, they can do little without the appropriate equipment. Those needs should be considered.

4. A plastic tackle box makes an excellent kit. It is tough, waterproof, relatively inexpensive, and doesn't look like a doctor's bag. Those qualities help make it durable, easy to replace, and less likely to be stolen. Best of all, it offers numerous small compartments which allow a flexible organization of its contents in any fashion desired (figure 2). This flexibility is at least one quality that makes it superior to commercially available emergency kits which generally have compartments preformed to accommodate specific drugs and equipment. Last but not least, one can sit on it if the bench is full and stand on it to better see the game.

5. The stocked kit is expensive. The total cost in 1984 would be five hundred and seventy-five ($575) dollars. It is worth every penny!

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After Fluoride Come Sealants: A New Epoch in Control of Dental Caries

James W. Bawden

THE benefits of dental research are having profound positive effects on the occurrence and pattern of dental decay in the American population, especially in chldren and young adults. These advances offer a bright promise of improved dental health for future generations.

There are extensive studies documenting the steady and significant decline in dental caries in most segments of the U.S. population. Depending upon the population group and the index used to measure the caries rate in the given study, caries reductions of up to 50% over the last 15 years have been documented. Those of us who have been seeing children in the dental office over the past decade and a half need no statistics to understand that many more children are caries free or have very few cavities than was the case in the late '60s. The child who suffers from rampant decay and severe destruction of the teeth is much less common these days. This change is of great benefit to the general health and well being of these young people and represents enormous savings in the cost of dental care for children and young adults. We predict that as these young people grow into middle age and later life these benefits will continue.

The biggest reductions in dental decay are associated with the fluoridation of municipal water supplies, but substantial reductions are seen in nonfluoridated communities as well, presumably because of the widespread use of fluoridated toothpastes and fluoride mouth rinses and the application of topical fluorides to children's teeth in dental offices. Other factors may be involved such as changes in dietary habits, improved oral hygiene, and increased exposure of children to antibiotics for medical reasons. However, the impact of these influences is not well defined and most of the credit must be given to the effective use of fluorides.

In addition to reducing the overall occurrence of dental decay in the population, fluorides have changed the pattern of caries distribution in the mouth. Fluorides are effective in preventing decay on all surfaces of the teeth, but are most effective on the smooth surfaces between the teeth and facing the tongue and cheeks. The chewing surfaces of the back teeth which contain deep pits and grooves receive less protection from fluorides. Consequently, dental decay in the young population is becoming primarily a pit and fissure surface disease. In children exposed to fluorides, particularly fluorides in the water supply, virtually all of the decay is found in the pit and fissure surfaces.

Fortunately, another breakthrough in research has given us a new weapon in the prevention of pit and fissure caries — the dental sealant. Sealants are plastic coatings that are bonded to the pit and fissure surfaces of the posterior teeth. Application of these sealants is relatively easy and painless. The procedure is noninvasive. That is to say, a dentist need not give an anesthetic injection and no tooth structure is removed in the process. When properly placed, sealants are highly effective in the prevention of pit and fissure caries.

To place a sealant, the tooth surface to be sealed is cleaned and isolated, usually with cotton rolls, so that it can be kept free from saliva contamination for several minutes. The enamel surface is etched with an acid solution that creates millions of micropores in the enamel surface. After approximately 1 minute, the etchant is rinsed from the tooth and the tooth is dried. The unpolymerized plastic sealant is applied over the tooth surface where etching has occurred and hardens either by autopolymerization or by activation with ultraviolet or strong white light. The curing process takes from 20-30 seconds. The procedure for a single tooth can be accomplished in a few minutes. The major difficulty is that certain teeth are difficult to isolate satisfactorily and contamination of the enamel surface occurs before the procedure can be completed. If contamination occurs, the sealant will fail to bond properly and will be lost immediately or during the next several weeks. If a good bond is achieved, the sealant will stay in place for many years and fully protect the surface from dental decay.

Sealants have been available for over 15 years, but their use has been limited. The first sealant systems were not adequately tested and the failure rate was very high. Dentists became discouraged with this initial experience and they have been cautious in using the method again. There are now numerous clinical trials that clearly document the effectiveness of sealant products now on the market. There was also concern that small cavities might be covered over with sealants and there was no research on the consequences. Several recent studies have shown that sealing over small areas of decay will simply arrest the decay process since the sealing action deprives the cariogenic bacteria of their critical nutrient, sugar. The bacterial population in such cavities declines rapidly and often disappears completely. The few bacteria that may remain cannot produce acid which is necessary for the decay to progress. It is now apparent that sealants are highly effective and that the original concern about sealing over small cavities is no longer a consideration.

In December 1983, the National Institute of Dental Research sponsored a conference at which there was a complete review of all the research relevant to the use of dental sealants. An expert panel developed a consensus report which was then presented to, and commented on by, the

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From the Dental Research Center, The University of North Carolina, Chapel Hill 27514.

audience of more than 500 interested scientists and clinicians. These comments were considered and a final draft of the report was produced and published by the Institute. The report has received considerable attention from the news media and has substantially heightened the awareness of the general public concerning sealants. It has also provided the dental profession with a comprehensive review and evaluation of pertinent research, and calls to their attention the scientifically documented safety and effectiveness of the method. The use of sealants by dental practitioners will probably increase substantially in the next few years and will have a most favorable effect on further reducing the caries level in our population.

Parents should rely on the clinical judgment of their dentist to decide if children should have sealants applied to their teeth. There are some children who are so resistant to decay that the use of sealants is a waste of time and money. There are others who are relatively susceptible to caries and will benefit greatly from the application of sealants to all of their pit and fissure surfaces. And in some children only selected teeth should be sealed.

These advances in the prevention of dental disease are exciting and will work to the health and well being of most of our population. They are another example of the benefits derived from the expenditure of federal tax revenues in support of biomedical research sponsored by the National Institutes of Health in the quest to more effectively prevent and treat disease. The cost of such research is considerable, but it is miniscule in the context of the improved health to be enjoyed by our population and the enormous reductions in the cost of maintaining good oral health.

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Professional Review Organizations

H. E. Strawcutter, M.D.

THE issue now, as it has been since Medicare and other third party reimbursement began, is not "whether" there will be review but "how" and "by whom."

With the advent of Medicare and Medicaid in 1965, the federal government immediately became the largest health insurer or third party payor in the United States. It was believed necessary, from the federal government's point of view, to institute some type of review aimed at insuring that services paid for by the government were medically necessary and of appropriate quality. However, the utilization review programs of Medicare and Medicaid were fragmented and tentative.

Rather than establishing one utilization review program, three programs were developed paralleling the structure of Medicare and Medicaid. The first system for utilization applied to Part A of Medicare, that is, to the hospital insurance program. The original Medicare law required that each hospital establish a utilization review committee as a condition for participating in the program.

The second attempt at effective utilization review dealt with Part B of Medicare, that is, with supplementary medical insurance. Responsibility for evaluating medical necessity of physicians' services (which represent 90% of Part B coverage) was given to the insurance carriers.

Under Medicaid, the state plan had to include provisions to safeguard against unnecessary utilization.

There were then three programs, each with the same objective, which were administered and conducted by different groups. By 1969, a substantial body of evidence was developed in Congress attesting to the failure of these programs to achieve their objective. Some of the most apparent problems were

1. utilization review activities under Part A of Medicare were, generally speaking, of a token nature and ineffective as a curb to unnecessary use of institutional care and services;
2. performance of the carriers responsible for payment for physicians' services under Medicare varied widely in terms of evaluating medical necessity and appropriateness;
3. the law did not provide the Secretary of the Department of Health, Education and Welfare the authority to deal with providers and practitioners on an individual basis — i.e., he could not bar Medicare payments to those whose abuse of the program had been clearly established;
4. there was insufficient professional participation in and support of claims review by carriers and intermediaries and consequently there was only limited acceptance of their review;
5. the processes did not provide for an integrated review of all institutional and non-institutional services;
6. review activities were not coordinated between Medicare and Medicaid.

In August 1970, Senator Bennett, chairman of the Senate Finance Committee, introduced into the Senate an amendment, based on the Professional Review Organizations concept originaly developed by the American Medical Association but substantially modified, to establish Professional Standards Review Organizations throughout the U.S. Senator Bennett's amendment was modeled in several major respects on prototype review organizations which local groups of physicians had established in various parts of the country. This amendment, one among hundreds of changes, was included in Public Law 92-603 . . . the Social Security Amendments of 1972.

Following the passage of Public Law 92-603 implementation of the Professional Standards Review Organizations (PSRO) law began. Groups of dedicated physicians formed local organizations and contracted with the federal government to review medical care delivered to Medicaid and Medicare patients. In 1972 there were no Professional Standards Review Organizations functioning. By January 1981 there were 187 conducting reviews.

Physicians and staff of the PSROs had to battle hostility and opposition from many sectors. The American Medical Association encouraged opposition to them. Some state Medicaid agencies fought them in an attempt to retain authority, and thereby funding, for state review. Some hospitals resisted the system, which they feared would place a curb on income. Some physicians battled against anyone reviewing the necessity and adequacy of care delivered to their patients. Cries of interference between a physician and his patient were heard here and there. Fiscal intermediaries resisted relinquishing review to states and to PSROs.

But PSRO physicians and staff persisted. They patiently explained that the program was physician-directed; that it was designed to ensure that physicians make final determinations on medical necessity and quality based on criteria developed by their peers; that membership in the progam was open to all practicing physicians in an area; and that its review was objective, designed to correct only inappropriate patterns of practice.

As PSROs became more experienced they began to make better and more difficult decisions. Providers and practitioners who continued with inappropriate practice patterns after they were warned were sanctioned. Those whose behavior was aberrant but not abusive to the point of requiring sanctions were placed on pre-admission certification, consultation, and other approaches aimed at changing practice patterns.

During the next decade, physician organizations, by trial and error, developed techniques and acquired skilled staff support to accomplish review. The original concept of a battery of physician-developed standards of care against which all review decisions would be made was aborted in

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From Lumberton Urology Clinic, 101 West 27th Street, Lumberton 28358.

the process of its birth. Instead, gradually a process of peer evaluation of inappropriate medical care evolved. With progressive sophistication, it became more effective in spite of opposition from our colleagues, from hospitals and the burdensome federal regulatory process which tried to dominate it.

As the cost of medical care increased and became the dominant force in the system, these organizations were increasingly measured, not by their impact on the appropriateness of care which they could affect but by costs over which they had virtually no control.

The present administration came to office with an avowed objective of federal deregulation in every area of our society and industries. Not only deregulation of airline, trucking, energy, and communications industries but also our health care industry. Regulation was to be returned to the forces of a free marketplace with competition to be the solution for all problems.

With present, socially significant and politically sensitive programs like Medicare and Medicaid in place, a pure free market is neither desirable nor attainable. With the Medicare program now costing more than a billion dollars every week, accountability became more pressing. Pressure began to mount, properly, from the Office of Management and Budget to switch the review process to the fiscal intermediaries where more regulated fiscal constraint could be exerted.

Certain congressmen, a majority in fact, more directly responsible to voters were reluctant to withdraw quality control of the system from the hands of the physicians. Under the leadership of Senators Durenberger and Baucus, legislation instead was drafted to reconstruct physician-directed review from a decade of experience. This new structure was signed into law with the Durenberger amendment to the Tax Equity and Fiscal Responsibility Act in the fall of 1982. The newly defined organizations were designated Utilization and Quality Assurance Professional Review Organizations.

Certain significant changes were made from the original Professional Standards Review Organization pattern. Instead of the original 200-plus areas, Professional Review Organizations (PROs) are conceived as basically statewide units. To encourage rather than thwart innovation the structure is less proscribed. They may, for example, be either non-profit or for-profit corporations. Funding is to be by a two-year objective-based contract rather than by annual grants. The cost is to be allocated directly from the Medicare Trust Fund as hospital cost under Part A rather than subjected to the insecurity of the annual appropriation process. Hospitals are required to cooperate in order to participate in Medicare payments. In the hope that the physician community would respond positively, they have been given exclusive bidding rights for the contracts — *but for only one year!* If no physician group comes forward with an acceptable proposal, the bidding process will then be open to any organization, including insurers or fiscal intermediaries, excluding only hospitals or other direct providers of care.

The specific duties of the PROs were not spelled out in the Tax Equity and Fiscal Responsibility Act but in the Social Security amendments, passed six months later in the spring of 1983. There was good reason for this vehicle.

There was great public debate and media coverage of whether or not the retirement age should be raised to 67 in 1990. There was emphasis on the political significance of bipartisan acceptance of these amendments proposed by a commission to save the Social Security System for all time, which incidentally had also been done only seven years before.

There was virtually no notice of the most significant change in the Medicare program since its enactment nearly two decades before — prospective payment system by Diagnosis Related Groups. Financing of care would no longer be allocated to hospitals on an open-ended cost reimbursement basis but by a pre-set price established by diagnosis. Equally remarkable was the fact that within six months this radical new approach was being phased into place.

With this new payment system and the resultant shift in financial incentives, the responsibilities of review organizations also shifted. Certain reasonable assumptions have been made regarding the effect of these new incentives. There will no longer be any cost-reimbursable incentive to keep patients in hospitals longer nor to do more tests and procedures. Review of length of stay and ancillary service review will now be accomplished intrinsically by the system not by the Review Organizations. Since payment will be made per episode of hospitalization, however, the indications for admission, re-admission and transfers within the system are not intrinsically controlled and must be regulated by the review process. The possibility of exceptional cases called "outliers" is acknowledged by the system but these must be certified as *bona fide* exceptions by the review process. Incidentally, the entire budget for hospital services by statute must be no more and no less under the Diagnosis Related Groups payment system than under the Tax Equity and Fiscal Responsibility Act "target rate" limits, and the outliers are to be no less than 5% nor more than 6% of the total.

The primary factor in the grouping process after establishing the principal diagnosis is the presence or absence of an operative procedure, either diagnostic or therapeutic. This may make a significant change in Diagnosis Related Groups pricing. Patients who receive certain invasive procedures therefore are to be selectively reviewed. Under the new system, payment depends not on the cost of resources consumed but on the diagnosis established by the medical record, which categorizes the admission to one of 470 specific payment groups. The validity of the diagnostic data on the record establishing this group must be verified by the review process.

Finally there is the intent that the new financial incentives will not compromise the quality of the care which Medicare beneficiaries receive. This quality review is also vested with the review process.

There are medically unjustifiable extravagances in the system at present. These are inevitable in a cost reimbursed system. That payment process is virtually at an end. Significant improvements in the efficiency of medical care delivery will emerge rapidly. There are serious concerns in many quarters about the potential effects of these efficiencies on the quality of the product, the outcome of medical care in the future. No one can assess these quality of care issues as accurately as the physician community.

These basically are the five responsibilities for which the

PROs will be contracting: 1. admission review; 2. outlier review; 3. procedure review; 4. Diagnostic Related Group validation review; 5. quality review.

Where are we today in this process? I indicated that the statutory authority for the review process predated by about six months the payment process. Contracting for the review process is of a much lower order of magnitude than implementing the payment process. The payment process is now about 70-80% complete. To date there have been no Professional Review Organization contracts signed. The reason is an interesting dichotomy within the administration. The Health Care Financing Administration, charged with the responsibility for implementing both programs, has been contending with every possible impediment which the Office of Management and Budget, another limb of the Executive Branch, could develop. The Office of Management and Budget is still hopeful of being able to eliminate physicians entirely from any control of the system and accomplish review with the more manageable fiscal intermediaries. After numerous technical delaying maneuvers, the requests for proposals by potential PROs were finally issued and except for certain waiver states those proposals were submitted April 27. The Health Care Financing Administration anticipates that contract negotiations will be completed and signed, and PROs will be in place by 1 July.

One basic precept inherent in the Durenberger proposal for PROs was to encourage innovation by review organizations. Contract objectives were to be individually negotiated to meet identified local circumstances. Delays generated by the Office of Management and Budget have now compressed the contracting time frame to a point where such individualizing is virtually impossible. Objective setting and the monitoring process by the bureaucracy were proposed to have a freedom of latitude also permitting innovation. Unfortunately, the request for proposals, when finally released, was highly proscriptive. The obvious intent of the Health Care Financing Administration is to require a consistency in contract proposals which will facilitate their review and approval by a simple check list procedure. Required objectives are rigid and designed more to develop national statistics which can be reduced to flip chart graphs for presentation at congressional hearings than to effectively assess the quality of care being delivered under the prepayment system. Battle lines are again drawn between PROs and the bureaucracy. The more things change, the more they remain the same.

We have looked at where we came from and where we are today. Now, where are we going with the concept of accountability by physician review? I believe accountability in our profession is overdue. There was a time when physicians were excused from accountability by a strange sort of mystical semi-divinity attributed to our profession. What we were able to do was more mystical than scientific, didn't make that much difference and really didn't cost much. We didn't have to be accountable. Nobody questioned. We would like to think we can still enjoy that immunity but we cannot. We are being questioned. Our accountability is being challenged. Not the least of these challenges is the rising flood of malpractice suits. I hate to see our professional accountability being relegated to our judicial system. We are being held accountable not only for quality but for cost. The new payment system incentives have resulted from a perceived lack of responsibility on our part to consider cost by those who pay for medical care for both public and private sectors. I am no more comfortable relegating our professional accountability to financial managers than to our judicial system. We are being held accountable, not only for our direct professional actions but for those we manage. It is estimated that 70-80% of the medical care resources consumed in this country are either performed or ordered by physicians. I do not try to deny that. I want that other 20-30%. Physicians should have the authority of all of the medical care our patients receive.

There was a time when patient care was exclusively a one-on-one doctor-patient relationship. We not only examined, diagnosed and prescribed but dispensed all the treatment there was. That time has long since passed. We are now supported by an enormous establishment of people and buildings and technologic equipment. We are more managers and decision makers in patient care but we still have the authority to determine the best course for our patients. There are many forces today striving to take away that authority. We cling to it tenaciously but if we are to keep that authority, we must be willing to accept the responsibility: accountability. In a profession, accountability takes the form of being willing to subject ourselves to the judgment of our peers. The corollary is a willingness to judge our peers. Both elements are necessary for professional accountability.

Today and in the foreseeable future we will be functioning in a system that is strange to us. We did not create the system but we have benefited from it and are part of it. Our primary responsibility is the care of our patients. We can only exercise that by retaining the authority over their care. If we use the system in that care, we must retain the authority over that system and we can do that only if we assure the accountability of that system.

There are dedicated physician groups all over the country who have organized PROs. I hope there are enough to do the job. They have trained a cadre of staff to assist them. This is not a volunteer effort but the providing of a medical service, and should be recognized and compensated as such. If previous patterns hold, and I see no reason they will not, the federal government will try to dictate the requirements and not want to pay what they are worth. That will be an on-going struggle. At present, the cost of review will be about three-tenths of one percent of the total Medicare budget which is not an unreasonable portion to devote to *quality assurance*.

And quality assurance will continue to be the dominant concern of the physicians involved. With new financial incentives to reduce the consumption of medical resources, these quality of care concerns take on a new dimension. The purchasers of care, particularly the federal purchaser, will continue to demand less cost. There are costs that can be eliminated. There are some that can be reduced. Some will undoubtedly increase. Patterns of practice will change. There will be winners and losers. There should be.

It is my hope that we can maintain and enhance the integrity and credibility of our profession and retain the authority to manage the care of our patients. I see professional peer review as the mechanism to accomplish that objective.

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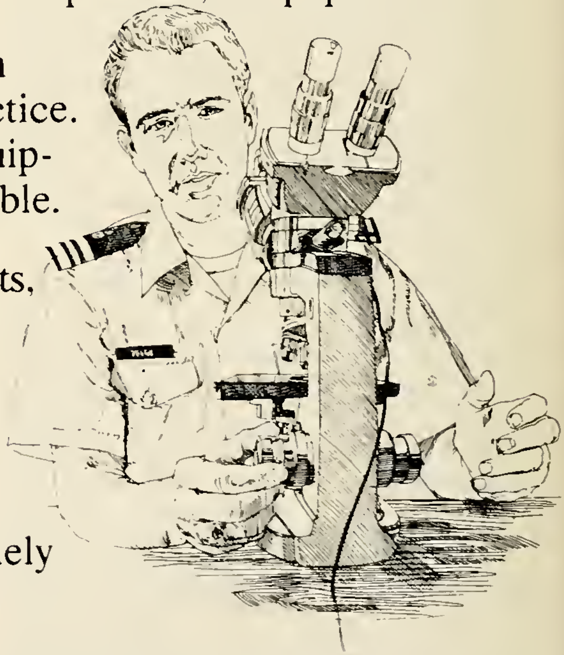

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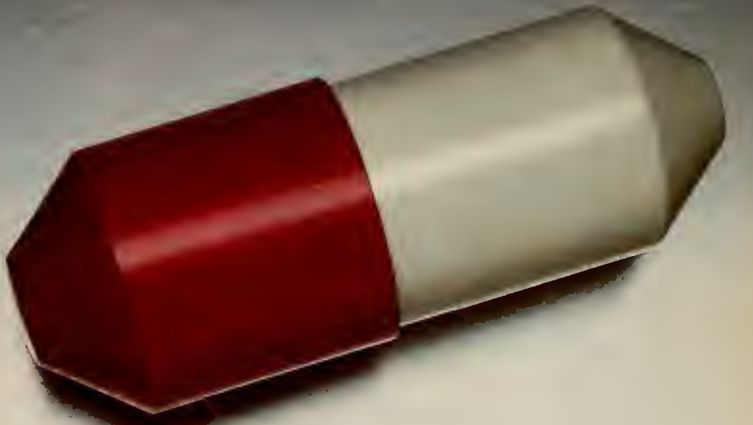

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Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K^+ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K^+ intake. **Associated widened QRS complex or arrhythmia requires prompt additional therapy.** Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function.

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Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth, anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions, nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

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OCCUPATIONAL MEDICINE

Adventures of a Latter-Day Carpetbagger

Leonard J. Goldwater, M.D.

ON January 31, 1984 some forty or fifty hardy souls braved a chilly wind to participate in a twenty-eight minute outdoor ceremony marking the opening of the Research Triangle Park office of the Occupational Health Service (OHS) of Duke University Medical Center. Present for the occasion were most of the individuals who had played important roles in the conception, gestation, birth and growth of OHS. Appropriately, E. Harvey Estes, Jr., M.D., Chairman of the Department of Community and Family Medicine at Duke, one of OHS's parents, presided over the proceedings. Others who spoke briefly were William G. Anlyan, M.D., Chancellor for Health Affairs at Duke, Ned Huffman, Executive Vice President of the Research Triangle Foundation, Susan Brown, M.D. of the Triangle Family Practice clinic and Lois M. Wysocki, Director of OHS. The ceremonial cutting of the ribbon to open the office was performed by Leonard J. Goldwater, M.D. who had the foresight to bring with him a pair of scissors large enough to do a proper job. (The "official" scissors were too small.) Incidentally, this snobbish gesture was characteristic of this Latter-Day Carpetbagger.* We shall hear more about those mentioned above, and about many others as the story unfolds.

In his remarks, Dr. Anlyan referred to his first encounter with the Carpetbagger which had taken place on or about January 2, 1967. The meeting had been arranged by Jay M. Arena, M.D. during a visit on December 27, 1966, the Carpetbagger's first contact with Duke. Thus it was Dr. Arena who opened the door. The Carpetbagger had established a beach-head in Durham. Earlier attempts to do the same in Chapel Hill had been unsuccessful.

Dr. Estes, too, dredged up a bit of history when he spoke of what had become known as "Goldwater's Folly." This refers to an abortive attempt in 1971 to set up a combined occupational and family medicine office in Parkwood, a residential community close to the Research Triangle Park. A pediatrician whose principal work was in Durham was then looking for someone to take over the lease on space he was renting. Included with the lease were the basic furnishings of a medical office, all at a bargain price. An added attraction was a clause in the lease whereby the owners of Parkwood agreed not to rent space to, nor to permit practice by, any other physicians as long as the lease was in force. It all looked too good to pass up, or so the Carpetbagger convinced Dr. Estes. But alas, the necessary staff and resources were not available and the project was abandoned after several months' rent had gone down the drain. Subsequent events, culminating in those of January 31, 1984, showed that the idea never died. It had merely lain dormant for a dozen years.

Also in the picture in the early days was another of the speakers at the opening — Ned Huffman who to some is Mr. Research Triangle Park. Following a visit from the Carpetbagger he arranged for the then Chairman of the Owners and Tenants Association of Research Triangle Park, Peter J. Chenery, to write to Dr. Estes on December 12, 1969 inviting him or his representative to meet with the Association to discuss ". . . the possibility of establishing some sort of occupational health facility to provide service to the tenants of the Research Triangle Park." The invitation was eagerly accepted, the meeting was held and shortly thereafter the first Research Triangle Park client, Burroughs-Wellcome Company, came into the fold.

The final speaker at the opening exercises, Lois Wysocki, entered the picture in 1982. There can be little doubt that if she had come to Duke earlier, the program would have been off and running several years sooner than was the case.

The Carpetbagger and His Early Days at Duke

Following visits to the Durham-Chapel Hill area in 1965 and 1966 the Carpetbagger decided that this would be an attractive place to operate following his retirement as Professor of Occupational Medicine, Faculty of Medicine, Columbia University in New York City. He was to be entitled to a sabbatical leave in 1967 and decided to make this a terminal leave and not return to Columbia at its expiration. He was anxious to attempt to write a book dealing with the historical aspects of mercury (quicksilver) and had obtained a two-year grant-in-aid from the Commonwealth Fund for this purpose. The folks at Duke graciously agreed to administer the grant and were perhaps pleased and relieved that no other commitment was required. They accepted the Carpetbagger's suggestion that he be designated a Visiting Scholar even though, as they said, this was a "first" for the Medical Center. A beachhead was now firmly established.

One requirement for a successful carpetbagger is to know what is going on in the place and field in which he is to operate. For the development of an occupational medicine program the ResearchTriangle Park appeared to offer fertile soil. Hairdressers and barbers usually are good sources of information, so the Carpetbagger decided to

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* Some who read this may recall from their studies of ancient history that it was the fate of southern nations and their cultures to fall prey to "Barbarians from the North." This epithet undoubtedly would be appropriate for some of the original Carpetbaggers of the 1870s. Its aptness in the present setting remains to be seen.

have his hair cut at the Parkwood Barber Shop, located just a few steps from where the new OHS office now stands. It was there that he learned about the medical office mentioned above and other matters of concern to him. It all looked encouraging. Potential client-companies were present in abundance.

Experience had taught, among other things, that when one embarks on a program of providing medical services in an organized way for groups of people, there are at least three questions that must be answered in the affirmative if one expects to be successful:

1. Is it legal?
2. Is it acceptable?
3. Is financial support available?

In this case *legalities* were chiefly concerned with the possible effects of a program that might earn a profit from the "sale" of medical services on Duke University's status as a tax-exempt institution. This was a particularly touchy matter since at that time the Internal Revenue Service was scrutinizing universities and other not-for-profit organizations. On the advice of counsel this possible danger could be avoided if a legally independent entity which would not claim tax-exempt status were set up to sell medical services. This was done in 1971 by the creation of Health Care Systems, Inc., as the agency which could make contracts with employers for providing a variety of health services. From the legal point of view it seemed not to matter that Health Care Systems was totally owned by Duke University and that it operated in a very close relationship with the Department of Community Health Sciences (later Community and Family Medicine). Profits after taxes, if any, from Health Care Systems were to redound to the benefit of the Department. A brochure prepared by Health Care Systems in March of 1979 noted that "Companies such as Burroughs-Wellcome, the National Institute of Environmental Health Sciences, the Environmental Protection Agency, the Research Triangle Institute, General Telephone Company of the Southeast, Liggett Group and General Electric are among the more than fifty firms relying on Health Care Systems for on-site and off-site medical services."

Acceptability involved several considerations. First there was the question of possible conflict with other interests and activities of the Duke Medical Center. This offered no problems since the services contemplated by the new program were in no way related to those already being offered at Duke. In fact, contacts and contracts with local employers for occupational health services could result in additional business for the hospital and for a variety of consultants.

Then there was the question of acceptability, or at least absence of opposition, on the part of the local private practitioners — the ever-present situation of "town versus gown." The fact that Dr. Estes had for some time been active in the affairs of the local and state medical societies facilitated a more or less painless resolution of this issue. Meetings were held with representatives of the medical societies at which the proposed program was explained, giving the local practitioners an opportunity to voice any objections. The physicians were asked whether or not any were currently providing occupational medical services to any local employers and if any were interested in doing so. This related to one of the missions of the Department of Community Health Sciences, namely, seeking out unmet medical needs and attempting to fill the needs. Some searching and even pointed questions were asked, but with consummate finesse Dr. Estes disarmed any potential opposition. The all-important question of acceptance by employers was one which only time could and would answer. About this, more anon.

Financial support for the program, at least in the early stages, was not a problem. A base of operations was provided by the Department of Community Health Sciences without appreciably increasing the overhead expenses of the Department. About the only cash outlay was for gasoline for the Carpetbagger's car as he went around calling on prospective customers.

A perennial problem in Occupational Medicine has been the provision to small enterprises of the same services that are economically feasible only to the largest through their own medical departments. An obvious answer is through collective action but this requires geographic propinquity of a number of small establishments and a nearby source of services. The Carpetbagger recognized that this combination existed between the Research Triangle Park and the Duke Medical Center.

The first local company to enroll in the program was a tobacco company which had not been solicited. This was in 1970. The company's physician was planning to retire and a replacement was being sought. This appeared to be a golden opportunity to get the program off the ground but it turned out to be something of a disaster. For one thing, the cost of providing the required services was grossly underestimated and secondly there was great difficulty in scheduling physician coverage by the limited staff available. In addition, one of the features of the plan that had made it attractive was the possibility of studying morbidity and mortality records of several thousand persons who were occupationally exposed to tobacco dust and who were given and who smoked liberal numbers of cigarettes. This was in the early days of the "cigarette scare" and appeared to be a golden opportunity to collect valuable epidemiological data. The company thought otherwise, perhaps not surprisingly. The final debacle came when employees reported to their supervisors that one of the Duke physicians was vigorously preaching about the dangers and evils of smoking. An escape clause was invoked and the contract was terminated in 1971.

The Carpetbagger had read Epictetus and remembered the words: "On the occasion of every accident that befalls you, remember to turn to yourself and inquire what power you have for turning it to use."[1] In this case, the use was that of the bellwether. It was most useful to be able to say to prospective clients that we were already providing service to one of the largest employers in the area. Even though the bellwether left the fold, other participants had begun to enter in increasing numbers.

While no large amounts of money were needed to initiate the service feature of the program two other aspects needed attention, namely, teaching and research. For these functions, no funds were at hand. In an effort to fill the gap the Carpetbagger established what he dubbed the Duke Mercury Research Fund in 1970. The designation "Mercury" was chosen for several reasons. For one thing, the Carpetbagger enjoyed something of a reputation as an expert in the toxicology of mercury which in the early 1970s was "the pollutant of the month." Some of his associates credited him with having achieved the "summum bonum" of the alchemists, that is, turning mercury into gold. For the occupational medicine program this meant a source of income through consulting activities and from industries that were facing problems relating to mercury in the working and general environments. Paradoxically, there was less difficulty in obtaining contributions than in getting the financial officers of the Duke Medical Center to set up an acceptable mechanism for receiving and disbursing the funds. This obliged the Carpetbagger to resort to some slightly unorthodox tactics, such as a sit-in in the treasurer's office, to achieve his objectives. By the end of 1983 the Mercury Research Fund had received more than 500 contributions from about 50 donors for a total of approximately $300,000. While not an impressive sum, it aided in research at Duke and, through modest grants, in six other universities. More important, however, were the financing of fellowships and traineeships in occupational medicine at Duke, the purchase of books, expenses for attending scientific meetings and holding four symposia dealing with occupational and environmental toxicology. Assistance in handling the Mercury Research Fund was provided by Margaret F. Jones, who, in 1978, became Mrs. Leonard J. Goldwater.

It may or may not have been sheer coincidence that the Carpetbagger was associated with mercury. The god Mercury (Hermes to the Greeks) was not only the messenger of the gods and bearer of the caduceus but also the patron of commerce, gambling, cheats and thieves, to name but a few of his interests.

In the early days the program was pretty much a one-man show with part-time assistance from the late Dr. Albert Hathaway, whose principal duties lay in the Duke Student Health Service. It was obvious, however, that if the program were to grow, additional participants would be necessary. Occupational medicine has never been a specialty that attracted any significant numbers of young physicians. A few Duke medical students had been taking the elective courses that were being offered but the number was small and none showed any inclination to remain in the field. In 1971 there appeared on the scene one Woodhall Stopford, M.D. who called himself Sandy and, incidentally, is a nephew of former Dean Barnes Woodhall. He was undecided as to what he wanted to do after he had completed a one-year internship at Duke hospital and another year as Clinical Scholar. The Carpetbagger suggested that he consider occupational medicine but not until he had served a two-year residency in internal medicine in preparation for Board certification in that specialty. This requirement is based on the fact that a top-flight specialist in occupational medicine must be prepared to hold his own with some of the sharpest internists (and lawyers). So Stopford went off for a two-year medical residency and on his return to Duke in 1973 agreed to try occupational medicine for six months to see if it appealed to him. It took less than six months for him to make his decision and he has remained as a key person in the program. With the passage of time he has taken over more and more of the work of the aging Carpetbagger. Despite the heavy demands on his time he managed to earn the Master of Public Health degree at the School of Public Health of the University of North Carolina in Chapel Hill. This academic training is one of the requirements for physicians who wish to become eligible for specialty board certification in occupational medicine. These details on Dr. Stopford's career have been given in order to illustrate the demanding standards set for the professional staff of the Duke Occupational Medicine Service. This does not mean that all physicians in the program have completed such rigorous training. There is a place and need for others.

A giant step forward was taken in 1970 with the acquisition by the Department of Community Health Sciences of the Marshall I. Pickens Building. This modern, spacious edifice became a home for a number of the activities of the department, including OHS. For the latter this was particularly important since most of the clients of OHS had no medical facilities of their own. Thus the Pickens Clinic became the medical headquarters for a number of local enterprises as well as for the Employee Occupational Health Service for some 15,000 employees of Duke University, the largest single employer in the Durham area. The first full-time director of the latter, George W. Jackson, M.D., was appointed in 1982.

The work of OHS has never been limited to local clients. Before coming to Duke the Carpetbagger had established consulting relationships with a number of industries in various parts of the United States and abroad. Most of these have been continued and many more added. This work has provided a source of income as well as sites that have been used in the training of physicians and medical students. In addition, long-term observations on workers in various industries have provided material for research.

In a simple ceremony on July 27, 1981 the Occupational Medicine Program in the Department of Community and Family Medicine was given formal recognition as an integral element in the Duke Medical Center with David C. Deubner, M.D., M.P.H. as Director. At that time the Carpetbagger was presented with a handsome chair. It may have been the hope of the donors that he would use the chair to take a back seat, but this he stubbornly refused to do. A plaque affixed to the chair contains the words: "To Leonard J. Goldwater, M.D., C.O.B." The last three letters stand for "Crusty Old Bastard," a title the Carpetbagger wears with pride.

Another important step in building the professional competence of OHS was taken in 1981 when Leon Golberg, M.B., B. Chir. joined the group. Dr. Golberg, a toxicologist and scholar with an international reputation and a distinguished career in England and in America, had been Founding President of the Chemical Industry Institute of Toxicology (CIIT) in the Research Triangle Park. He resisted an invitation from CIIT to continue there upon completion of his five-year contract and decided instead to accept a post at Duke in OHS. This choice was made in the face of many attractive offers elsewhere. He has made and continues to make important contributions to the teaching, research and consulting activities. His presence has helped to cement relationships between Duke and CIIT.

Teaching and Training

Starting in the early 1970s elective work in occupational medicine was offered to undergraduate medical students but not many were attracted to these courses. It was never entirely clear how many of those who signed up did so because of genuine interest or because the hours and credits suited the convenience of the students. In either case a dozen or so Duke graduates left the medical school with some idea of what Occupational Medicine was all about.

In 1976, Patrick R. Conner of Burlington, North Carolina, then a third-year medical student, chose to take elective work in Occupational Medicine. He later (1984) confessed that this had been a matter of convenience but he became so interested in the field that in his fourth year he spent a full two-month rotation at an occupational health teaching center in a distant city. After completing his internal medicine residency he returned to Durham and supported himself and his family by working part-time at the International Business Machines Company in the Research Triangle Park while earning his Master of Public Health degree at the University of North Carolina and attending the weekly OHS seminars. He may be considered to be one of the first two full-fledged products of the Duke Occupational Medicine training program. Conner was succeeded in 1978 by William B. Bunn, III who, following his elective studies, was awarded a Mercury Research Fund Fellowship for nine months while awaiting the start of a medical residency at the Duke Medical Center. Bunn, incidentally, had taken the combined M.D.-J.D. curriculum at Duke and later earned the Master of Public Health degree at the University of North Carolina in Chapel Hill. Upon completion of this rigorous program he was appointed on January 1, 1984 to a full-time position in the OHS. Of some significance is the fact that during Bunn's medical residency he was permitted to spend a certain amount of his time with OHS. A part of this time was devoted to exploring and developing relationships between the medical service at Duke Hospital and OHS, particularly in two-way consulting activities. This arrangement was formalized in March of 1984 when Bunn was given a joint appointment on the medical service of Duke Medical Center. Like Conner, Bunn is a native of North Carolina, having grown up in Raleigh.

Short-term fellowships similar to that held by Dr. Bunn have subsequently been given to several recent graduates of the Duke Medical School and continue to be available.

Between 1979 and 1983 the teaching program was kept alive largely through the devoted efforts of John W. Cromer, Jr., M.D. who continues to play a role along with Dr. Stopford.

UNC and OSHERC

Although the Carpetbagger had been shunned at the University of North Carolina in Chapel Hill when he first arrived in the South, he later was offered and accepted a teaching appointment in the School of Public Health. This was in 1970 and it marked the beginning of a relationship between UNC and the Duke OHS that was to become increasingly close. The first UNC faculty member to become involved with OHS was Ted Williams, an industrial hygienist, who provided valuable assistance in the days before OHS employed its own industrial hygienist, Gary Shaver, in 1979.

Additional ties between the sister institutions evolved, starting in 1977, with the establishment of a regional Occupational Safety and Health Educational Resource Center (OSHERC). North Carolina State University in Raleigh was also involved in this activity. The North Carolina OSHERC program was one of about a dozen that were organized in various parts of the country to take advantage of Federal funds administered by the National Institute of Occupational Safety and Health (NIOSH), the principal purpose being to provide continuing education for individuals concerned with various aspects of occupational health. Primary administrative responsibility for OSHERC was assumed by the School of Public Health at UNC which had a strong program in industrial hygiene but was weak in medical aspects. The Duke OHS provided physicians and N.C. State covered safety engineering and related areas. Physicians from the Duke OHS have been major participants in many of the OSHERC activities including two annual week-long teaching "institutes" for occupational health professionals. Weekly seminars attended by students and faculty represent another joint effort of the three Triangle universities. These sessions are open to all interested persons and attract representatives of local industries, health officials and others. In 1984 NIOSH rated the North Carolina OSHERC program as the best and the Duke medical component also as the best in the country. It was gratifying that the high standards of the Duke OHS should have received this recognition.

Residency Program

As the occupational medicine program grew it became apparent that a possibility existed for it to become a major center in its field. One feature would be an accredited residency training program designed to prepare candidates for certification by the American Board of Preventive Medicine (Occupational Medicine). One of the requirements, an academic year in a school of public health leading to a Master's degree, was readily arranged through the School of Public Health of UNC. Resources of OHS were suitable for the clinical and practical experience necessary to meet the Board requirements. Conditional approval was granted by the Residency Review Committee in 1981 and full approval in 1984.

Some question exists as to who should be given the distinction of being the first resident physician. As mentioned above, Dr. Bunn served a part of his residency in the OHS by arrangement with the Department of Internal Medicine where his principal appointment lay. First to enroll as a resident for the full two-year term was Gary N. Greenberg, M.D. who served from July 1982 to June 1984. At the time of this writing (March 1984) selections are being made from among several dozen applicants for the next group of residents. Preference is being given to those with a strong background in Internal Medicine.

What of the Future?

The literature contains conflicting views of the usefulness of the past in predicting the future. Edmund Burke (1728-1797) said that "You can never plan the future by the past,''[2] and Adelaide Ann Procter (1825-1864) of Lost Chord fame declared that ''The past and the future are nothing.''[3] On the other hand Gottfried Wilhelm Leibniz (1646-1716) has been credited with saying that ''The past is pregnant of the future'' or some German words to that effect. It is not clear whether or not this view was one of the reasons why Voltaire (1694-1778) made Leibniz a particular target for ridicule in *Candide*. Voltaire notwithstanding, our brash Carpetbagger chooses to accept Leibniz over the other experts on prognostication.

There are several reasons for predicting that the Duke OHS will continue to grow. Not the least important of these is that the Carpetbagger is no longer the only player in the game. A team of high calibre has been assembled, they know what to do and how to do it, and recognition of their capabilities is gaining wide acceptance. Nationwide, concern with occupational health and related areas such as environment and hazardous wastes is growing. There is, of course, a certain amount of competition, but few individuals or groups can offer the resources, quality, experience and professional competence that has been assembled at Duke. (If this sounds like a ''commercial'' it is intended to be just that.) The large number of applicants for training in the Duke OHS program is but one evidence of this group's high reputation.

Among plans currently under consideration is a proposal for a Center for Toxicologic Medicine. To quote from a document prepared in August 1983, ''This center would be multidisciplinary and would specialize in the highly sophisticated clinical evaluation of persons suspected of having effects of toxic exposures and the integration of that evaluation result with investigation of the toxic exposure to arrive at judgments of their interrelatedness.'' In essence this would be an extension of one of the traditional roles of Duke Medical Center in dealing with difficult or complicated medical problems.

The future looks bright. The Carpetbagger apparently knew what he was doing when he moved into North Carolina.

Postscript

''The living legend . . . is a vulnerable creature. His life's work completed, appraised, classified, he alone remains at large, uncertain and unpredictable. . . .''

Kevin Brownlow
The Parade's Gone By

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PHYSICIANS' FORUM

Ideal Work Week

Eugene W. Linfors, M.D., editor

Will doctors of the next generation be less productive because of a trend toward the shorter work week? Is there an ideal work week for the practicing physician?

From Dr. John R. Chambliss, an internist in Rocky Mount.

These are two interesting and provocative questions. Most of us equate production with money. If you will allow me to do so, I would then ask the first question in different words, namely, "How can I have more time off and make the same or more money?" I find the priorities of the younger generation somewhat changed from those of we older physicians. As usual, I think that they are correct. There is little merit in continuing the old customary 60-hour week. I do believe physicians deserve more time for their families and recreation and I think this will contribute to their efficiency. To have a shorter work week, however, and maintain production or income is going to be difficult. This only can be done by more efficient utilization of one's working hours (when do you go to all those hospital committee meetings?) or by raising fees. More and efficient use of time means greater dependence on ancillary help (and thus more employees and increased overhead) and having the physicians do only those things physicians alone can do. I find young physicians most willing to work long hours. They do wish to work a shorter work week and wish some reasonable degree of protection from night work by cross-coverage. I do think they are quite willing to work longer days and less days a week.

Raising fees, which are probably too high now, in the current environment is unacceptable. I believe that the super specialists can obtain these two goals, namely a shorter week and the same or greater pay. I do not think those of us in primary care can do so. It is quite possible when the "doctor glut" fully materializes we may have a shorter work week whether we like it or not.

I do not know the answer to the question, "What is the ideal work week for physicians?" I have great fear that external factors are going to determine this for us and we may have a complete change in our life style. Our hospitals are struggling to survive under DRGs. If we are going to survive, our hospitals have to survive. Can our hospitals afford to close down operating rooms and supporting services two out of seven days? I tend to doubt that they can do this and survive DRGs. If the hospitals are going to work seven days a week, then the physicians are going to have to work seven days a week. This can only be accomplished by organized cross-coverage and a change in the pattern of a physician's life style. It may be that our "weekend off" in the future may be days in the week other than Saturday and Sunday. Perhaps the "doctor glut" will help solve the problem of the shorter work week but I do not see how it can maintain production (money). The same pie will simply be cut into smaller pieces.

It will be only in rare instances that the goals of a shorter week and maintenance of production can be achieved. Perhaps in the future we will learn that more time off is worth the price.

From Dr. Theodore R. Clark, a psychiatrist in Pinehurst.

In response to the above questions, some doctors undoubtedly will be less productive, other doctors will leverage their time with computers and ancillary personnel. "Is there an ideal work week for a resident physician or practicing physician?" Yes — 40 hours.

From Dr. Dan Constien, chief resident in family medicine in Greenville.

When asked whether the doctors of the next generation will be less productive because of the trend toward a shorter work week, I wonder what is meant by "productive." Does it mean the number of patients seen, the number of surgeries performed, the amount of money made, or does it reflect the quality of care that is rendered? As a resident in Family Medicine, I often feel like the woman with 13 children who when asked if she had enough time to take care of all her children replied that when she had only one child she didn't have enough time.

So many times, I have wished that I had more time — time to counsel an anxious or depressed patient, time to review nutrition, safety, or stress reduction with a patient who comes in for other reasons, time to work in the walk-in patient without causing undue waiting time for the others, or time for myself — reading or recreating.

Is there then such a thing as the ideal work week for a resident or practicing physician? The answer is an individual one based on the quality of care one wishes to give, the quality of life one wishes to live, and for most, time will always be too short.

From Dr. Conrad Fulkerson, a psychiatrist in Durham.

With productivity in medical practice defined very basically as the effective and efficient evaluation and treatment of health status and/or problems of individuals, I believe that the physicians of the next generation will be equally or even more productive than their predecessors despite a shortened work week.

The factors that will influence physicians and their patients in the years to come are so numerous, broad ranging, and varying in their potential effects that the shape of future medical practice, including level of productivity, is extraordinarily difficult to predict. Particularly confusing are factors somewhat beyond the traditional biomedical sphere such as the overall economics of medical care; changing expectations, lifestyle, and sophistication of both patients and physicians; and the revolution in information storage, processing, and transfer (even as I write this opinion on a word processor). I do not pretend to have considered and weighted all of the possible influences and my contention of equal or greater productivity may be as much a personal attitude reflecting my general optimism (looking forward to a few days away) as much as anything close to an informed prediction. Nevertheless, it seems to me that we are generally working smarter, more effectively, and more efficiently in most areas of life, including medical practice.

I believe that there are some particularly important determinants in this trend toward greater productivity in medical practice. The "slack" in medical practice of past years in terms of repeated tasks performed with unnecessary investment of time and energy, data "hand carried" in office and hospital, and record keeping systems akin to those of scribes of biblical times (to mention but a few examples) is being taken up and this will continue at an advancing rate. Second, demands from consumers and financial intermediaries in medical care are clearer, more consistent, more informed, and less ignored than ever. Finally, we seem to repeatedly rediscover just how work may expand to fill time available in which to do it and seem to gradually become less tolerant of burdening ourselves unnecessarily.

In my own practice of outpatient psychotherapy-based psychiatry I have had, against the dreary background of the psychiatrist's famous compulsive adherence to routine of schedule and procedure, some opportunity to observe myself more carefully than in the preceding five years during which I seemed to be always running about while engaged in training and then brief practice of internal medicine. A lesson that I have learned (and relearned over and over) is the subtle effect of fatigue on my capacity for focus of attention, mental processing of information, and experience of my own affective state. With the consistency of seeing the same individuals session after session in the same setting dealing with aspects of the same issues I note a significant difference in my functioning depending upon whether I am stressed, overworked, or recently vacationed. The fact that I can conduct apparently passable psychotherapy in a relatively fatigued state sometimes frightens me when I find just how much more effective I can be when rested. My productivity (my capacity to make some usable sense out of the material that the patient is presenting at the time such that the patient himself may be better able to think, feel, work, etc.) seems highly dependent upon the amount of work I attempt to do in any given period of time and the opportunity for such serially controlled experiments (working in simple and consistent circumstances both rested and fatigued) has convinced me that many times both in my training and in my practice I have worked on the "down side of the Starling curve" in that my continuing efforts sometimes become progressively less efficient the more I "stretch" myself.

Whether such observations are transferable to the general practice of medicine or to other individuals could be debated but I submit that the activities of receiving and processing information and then making and implementing decisions based on that processing are central to thoughtful medical practice. I conclude, based on these observations, that (1) mental and/or physical fatigue significantly affects my work and "productivity"; (2) though the diminution in my effectiveness seems somewhat linear with cumulative fatigue, there are points at which attempts at continued work seem to more rapidly decrease productivity; and (3) with the fatigue occurring gradually and with frightening subtlety, I do well to give attention to the amount of work I schedule for myself and the commitments I make for any given period of time.

Given the peculiar aspect of human frailty that seems to distort our ability to know ourselves with progressive fatigue, "burnout," or intoxication, I believe that there is a case for attempting to determine and implement a personal "ideal work week." There are a great many variables that figure in such a determination and it is difficult to consistently closely approximate this ideal in practice week after week. I do believe, however, that most individuals can, with some reflection, introspection, and possibly feedback from others in their environment make some determination of their own capacity for productive work within a given period of time. Scheduling and structuring time away from work for activities unrelated to work are critical for most physicians to achieve this since most of us relate to idle time the way that nature deals with a vacuum. The physician, surrounded today by remarkably complex and diverse instruments, is still primarily his own most important tool and, as such, deserves the finest care, certainly equal to the care given today to key business executives or athletes.

From Dr. William P. J. Peete, a surgeon in Durham.

In my view doctors of the next generation will not be less productive because of the trend toward a shorter work week. There will be greater efficiency because of advances in technology such as NMR and in the use of technology. Undergraduate and graduate students are at least as intelligent as past ones, and continue to be highly motivated to excellent patient care, teaching and research. I think the doctors of tomorrow will find ways to tilt at fewer windmills, those impossible situations where we spend so much time and money and produce so little, sometimes only grief. This will come about because of wise patient wishes, greater soul searching by physicians and financial pressures to reduce medical costs. Financial pressure will also make research more efficient. Actually a shorter work week in itself may create greater productivity: the heart rests more than it works. The great surgical producer William S. Halsted was notable for three and six month vacations. For the problems which face them, the doctors of tomorrow may indeed find solutions in a shorter work week. If not, despite the trend toward a shorter work week, they will spend the time needed to solve them.

I doubt there is an ideal work week. There may be an ideal work goal. Dr. Richard Cabot, well known for beginning clinico-pathologic conferences and social service, felt strongly that full development of a physician required he learn to and continue to work and play, to love and worship in a balanced way according to *his* capacity. Dr. James T. Cleland once told a colleague at Duke University that his colleague's sin was not that he loved the University but that he worshipped it. For the physician it may be important to substitute medicine for University to reflect upon false Gods. I think the ideal work week will vary with the time in one's life and his capacity and needs at any one time, not just residency and practicing physician. For example some need only four hours sleep. Some find play and love in work. Even so, the tendency for the modern physician and the system in which he works is to overfocus on work; to permit neglect of play, love and worship, and to suffer because of both. If one works with Cabot's convictions and Cleland's nuance in mind, then a successful work week can vary between less than forty to more than a hundred hours a week.

From Dr. William B. Tarry, Jr., a family practitioner in Oxford.

In company with most other productive groups of one kind or another, physicians for many years have pursued means of shortening their working hours and securing more leisure time — the pursuit always modified by reluctance to take a cut in income in order to do so. Group practices have multiplied in number and continue to grow in size. Emergency rooms have provided more and more acute (and even chronic) care outside regular working hours. Establishments providing 24-hour care for acute illness or "minor" trauma have burgeoned in urban areas. Paramedical people now provide a significant amount of medical services.

Most of this change is the result of changing public demand rather than a concerted physician effort to shorten working hours. Patients are ever more knowledgeable, confident, and secure in asking for what they want. Much innovation and change in medical care will result from increasing patient independence. More emphasis will be placed on what they want rather than what we think they need. And it is about time.

Will these changes and pressures reduce the productivity of the new generation of physicians? I don't think so. Physicians have not changed — their public image has. The new group is composed of exceptionally intelligent, decently motivated and well trained professionals whose education has progressed with the times. There are those among them who will choose the regimented stable conditions and regular hours of emergency rooms, acute care centers, and institutional work as well as the less patient oriented specialties. Large numbers also will eagerly accept the challenge, the responsibility, and the privilege of providing comprehensive medical care. They will find new ways to do more in less time but they will not be less productive. They will charge more but it will be worth the cost.

We live in a small town of about 10,000 with a 65 bed general hospital and serve a population area of perhaps an additional 15,000 people. The hospital staff includes six FP's (our group of two, one group of three, and one solo), two independent internists, one OBGyn and two general surgeons who are partners. All are in full-time practice, hospital and office. Our average work week is about 65 hours which includes administrative and staff duties as well as patient care. The accuracy of this figure is open to some question because some of these fellows sometimes can't tell the difference between what they do for a livelihood and what they do for fun. If you ask their wives for an estimate of their spouse's working time, the number of hours is almost invariably longer. I don't know what this means. None of us feels overworked. Although there is much wistful talk of "more time off," nobody seems to be doing much about it except for the trading of calls between individuals and the regular time-sharing within groups. A new physician moving into this area should expect to devote at least as much time, perhaps more, to establishing and maintaining a practice, whether in a group or solo.

Life and medicine are becoming no less complex. House officers should not expect to clock less time in their introduction to the profession; 90-95 hours weekly as a minimum does not seem unreasonable.

● EDITOR'S NOTE: As I read our sample of opinions I hear both optimism and a little uncertainty. By more efficient use of such aids as word processors and new diagnostic tests we can be more productive in fewer hours. However, external factors may determine our work week as much as we ourselves do. I don't hear any philosophical objection to a shorter work week.

North Carolina Medical Journal

Features for Patients August 1984

Communication for the Speechless Person

Jennifer Horner, Ph.D.

The purpose of this article is to describe the role of technology in communicating with adults who because of injury or disease have partial or complete loss of speech. We begin with some definitions.

Neurologic problems interfering with speech may occur suddenly or they may progress slowly over time. The major types of communication problems resulting from neurologic damage are *dysarthria* and *aphasia*.

Dysarthria is a speech problem resulting from damage to the central nervous system or peripheral nervous system that causes muscles producing speech to become weak, slow, or incoordinated. The quality of speech is likely to be altered when muscles important to breathing, voicing, and moving the soft palate, the tongue, and the lips are impaired. People with dysarthria are unable to speak normally because of impaired muscle function.

Aphasia is a language problem resulting from damage to the central nervous system, usually the surface of the brain. Aphasia may involve problems understanding what others say, problems expressing ideas with words and sentences, or problems reading and/or writing.

Thus both dysarthria and aphasia result from damage to the nervous system. Dysarthria is a speech problem that affects how quickly, evenly, or clearly we speak. Aphasia is a language problem that impairs our ability to understand or express in words and sentences. In neither dysarthria nor aphasia *per se* is the person necessarily confused. In both dysarthria and aphasia the degree of the communication problem spans a broad and complex continuum: the problem may be mild, moderate, severe, or profound. If speechlessness occurs, the problem may be described as profound. Some speechless individuals have the potential for communication by means other than speech and can be helped by modern technology. The technical term for these communicative systems is "augmentative communication systems."

Incidence and Prevalence

Dysarthria. About 14 of every 1000 persons in the population have some form of neurologic disease.[1] Each year approximately 8 persons of 1000 in the general population are newly affected with a neurologic disease. The ages at which progressive neurologic diseases are likely to occur differ. For example, multiple sclerosis usually begins between 20 and 40 years; Parkinson's disease, after 50; and amyotrophic lateral sclerosis, between 40 and 60.[1]

Aphasia. The major causes of acute or sudden onset neurologic injury are head trauma and stroke. Each year, approximately 10 of 1000 Americans will sustain a serious head injury, usually as a result of automobile accidents. Though head injury may occur at any age, young adults are most often the unfortunate victims.[2] Unlike head injury, stroke is related to age. Under the age of 35 stroke is rare; under 45, infrequent. Among persons 45-54 years, stroke occurs in 1 of every 1000; among those 55-64, about 4 of every 1000; among those 65-74, 9 of every 1000; and among those over 75, 30 of every 1000.[3]

Rehabilitation

The number of persons with either dysarthria or aphasia is unknown. According to an HEW report, of every 100 people who survive a stroke ". . . 10 will be able to return to work virtually without impairment, 40 will have mild residual disability, 40 will be so disabled as to require special services, and 10 will need institutional care."[3]

The concept of rehabilitation is not a new one but the conviction that "rehabilitation helps" is extending beyond health professionals to the general community. Several publications from the National Institutes of Health[4-6] describe developments in biomedical, social and behavioral research that help us appreciate the breadth and importance of human services and delivery systems. The goals of ongoing federally funded research and the goals of existing rehabilitation programs are compatible. For persons with an acquired

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neurologic problem, the goals include: 1) to minimize the degree to which an impairment becomes a disability, 2) to reduce and prevent dependency, 3) to raise the expectations of the patient, family and others in the patient's environment, and 4) to meet these objectives by providing opportunities for change. While the speech/language pathologist is usually the person directly involved with rehabilitation of the communication-impaired person, many other professionals contribute to the greatest possible rehabilitation of the patient. Depending on the specific setting, the rehabilitation team may include the neurologist, orthopaedic surgeon, other physician, rehabilitation nurse, physical therapist, psychiatrist, neuropsychologist, social worker, vocational rehabilitation counselor, and prosthetic, orthotic and environmental control specialist. The multidisciplinary rehabilitation setting is ideal for the speechless person who has potential for using an augmentative communication system.

Augmentative Communication Systems

Following head injury or stroke, or during a progressive neurologic disease, an individual may be unable to communicate orally and so need technologic help. The person with some residual speech may use aids to augment speech; the person who is speechless will use such aids to replace speech. A variety of factors influence what type of augmentative communication system is most suitable for a speechless individual. These factors include physical ability, language ability, and the ability to think.

Physical Ability. Some individuals with neurologic disease causing them to be speechless may have full use of their arms and legs; others may have limited use; others may have no use. The individual's ability to adopt to or compensate for a physical disability may depend on his response to physical therapy and/or the use of braces or supports. The most physically impaired person may have to rely on residual movement abilities such as head turning and tilting or eye blinking. A person's ability to move a body part voluntarily and consistently, and the range, strength, accuracy and speed of movement are important considerations.

Language Ability. It is necessary for the augmentative communication system user to have some language ability. A person with a profound dysarthria and a significant degree of aphasia will have to rely on the most basic of communication aids. In contrast, the person with a profound dysarthria and no aphasia is a good candidate to use a complex communication aid.

Ability to Think. The thought processes underlying communication depend on adequate attention, perception, memory, behavioral self-control, and a wide variety of other factors. The simplicity or complexity of an augmentative communication system depends to a great extent on the individual's general intellectual state and on the motivation to use the system provided. The Rancho Los Amigos Hospital[2] has developed an extremely useful approach to assessing the cognitive status of head-injured adults. Their "Levels of Ability to Think" describes 8 levels of functioning. Level 1, the lowest level, describes the patient who appears to be in a deep sleep and completely unable to respond. Level 8, the highest level, describes the patient who is alert, able to learn, independent in home and community skills, etc. The patient at this highest level is usually below his pre-injury level but is functional socially, emotionally and intellectually.[7] In my experience, a head-injured patient must be functioning at least at Level 6 and ideally at Level 7 or 8 in order to use an augmentative communication system.

Once the several facets of the speechless person's capabilities are determined, the speech/language pathologist can select the appropriate technologic system. There are three broad levels of difficulty: 1) basic, 2) intermediate, 3) complex. The successful use of an augmentative communication system depends on an

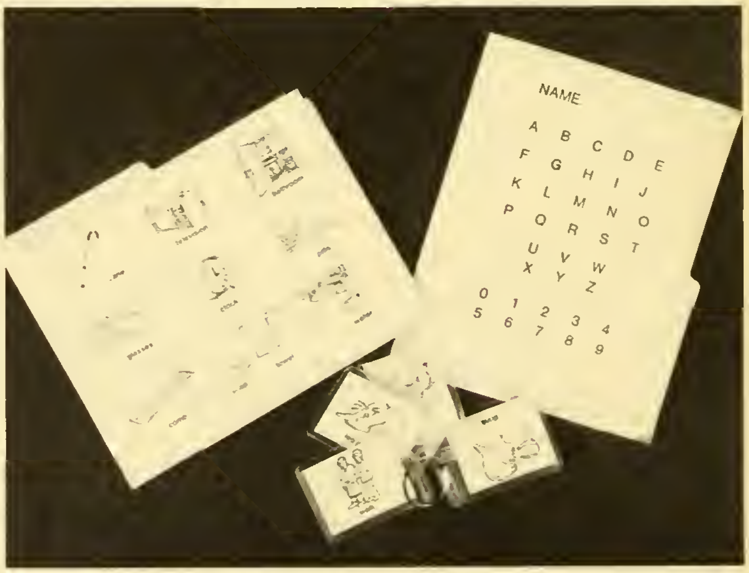

Figure 1. Three basic augmentative communication systems: Picture board; picture communication ring (illustrations from *Talking Pictures*, Crestwood Co.); alphabet board.

appropriate matching of the capabilities of the user with the complexity of the system. For this reason, it is important that a trained professional conduct an evaluation and observe the use of the system before the system is fully constructed or purchased. The professional consultant is also responsible for training the user and other important persons in the user's environment, as well as calling on other professionals who can assist in adapting the system to the specific requirements of the user. The following review of systems is selective, to give the reader an idea of the types of systems available. Other approaches and systems are available (see appendices).

Basic Augmentative Communication Systems are typically designed for the brain-injured adult who is speechless due to a combination of dysarthria and aphasia. The ability to perceive complex visual material (such as printed words) may be impaired, or the ability to use a wide range of vocabulary words may be impaired.

Figure 1 shows three basic and easily constructed augmentative communication systems: a picture communication board, a picture communication ring,[8] and an alphabet board. They require some manual dexterity, such as pointing, and they assume that the user is able to select reliably from the pictorial or alphabet display. All have the advantages of being light, portable and virtually cost-free. The alphabet board has the advantage of allowing the user to communicate a wider range of ideas, but of course the user must be able to spell. A pointing board comprised of organized lists of frequently used words can also be constructed.

The ZYGO augmentative communication system shown in figure 2 is a 16-item display that can be readily individualized, either with printed words (as shown) or pictures. The ZYGO is suitable for the speechless patient who has limited use of his arms. The user of a ZYGO system scans the board by using a remote switch and stops the scanning light at the item he wishes to communicate.

Figure 3 shows a variety of switches that are used to adapt to the needs of the individual user who wishes to activate a system like the ZYGO. Other adaptations for basic communication systems include light beams or pointers strapped to the user's head. For the user who desires a broader "vocabulary," a ZYGO with a 100-item panel is available.

Intermediate systems are relatively broader in their application, have a more complex letter/word or picture display, and/or use an artificial voice. The user must have a fair degree of language ability — including the desire to communicate a wide range of ideas — to use these intermediate augmentative communication systems effectively.

One type is the Canon Communicator (figure 4). This is a modified alphabet board, with letters organized by the frequency with which they are used in the English language, along with numbers and punctuation marks. An overlay is provided for the patient who has difficulty with very fine motor coordination. An attractive feature of the Canon Communicator is the use of a tape on which the printed message is permanently recorded.

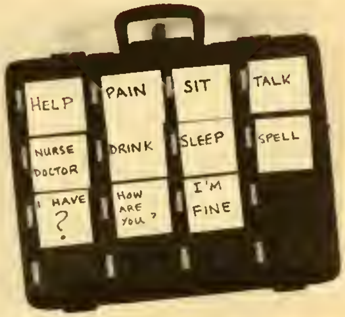

Figure 2. A ZYGO communication board with light scanner (ZYGO Industries, Inc.)

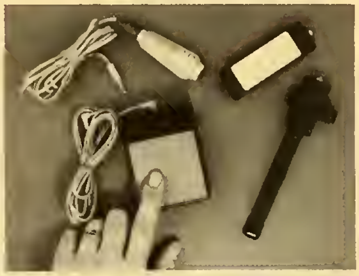

Figure 3. Adaptive switches for the augmentative communication system user who is physically limited.

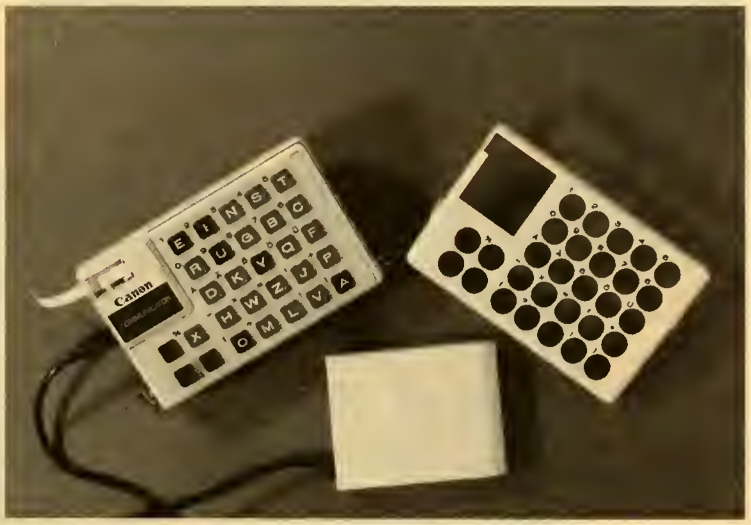

Figure 4. A Canon *Communicator* with battery pack and overlay (Telesensory Systems, Inc.)

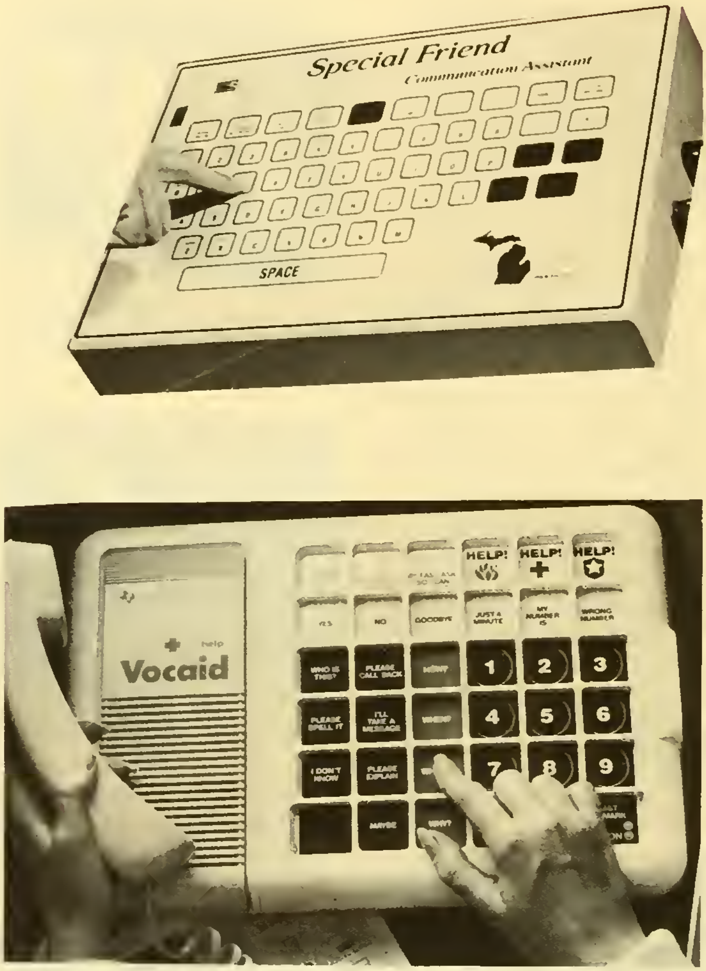

Figure 5. Two artificial voice systems: *Special Friend* (Shea Products, Inc.), and *Vocaid* (Texas Instruments).

The three artificial voice systems selected for illustration (figure 5 and 6) use touch-sensitive panels to activate them. They vary in the complexity of the visual display but are similar in that words (or pictures), sentences, letters, and numbers may be selected. They share the special feature that messages are conveyed by way of a synthesized (electronic) voice.

Complex augmentative communication systems are designed for the person who is physically limited but cognitively and linguistically normal or near-normal. Complex systems require good learning ability and motivation and are usually computerized and therefore more difficult to operate. Several systems include the feature of an artificial voice. Though usually more expensive than basic and intermediate systems, complex systems offer the distinct advantage of allowing the speechless patient with good language not only to communicate but also to learn and create.

Prentke Romich Company has produced a wide variety of complex communication systems, some of which are shown in figure 7. They have devoted research funds to the compilation of a comprehensive chart summarizing the many features of 44 commercially available aids manufactured by both Prentke Romich and other companies.[9] (See appendices.)

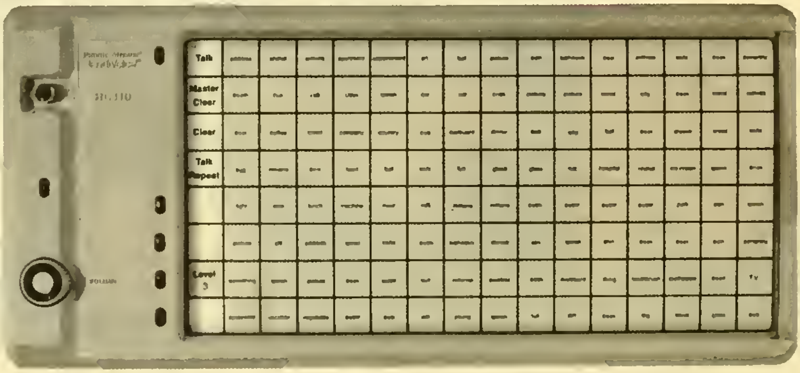

Figure 6. The *Handivoice 110* artificial voice system (Phonic Ear, Inc.)

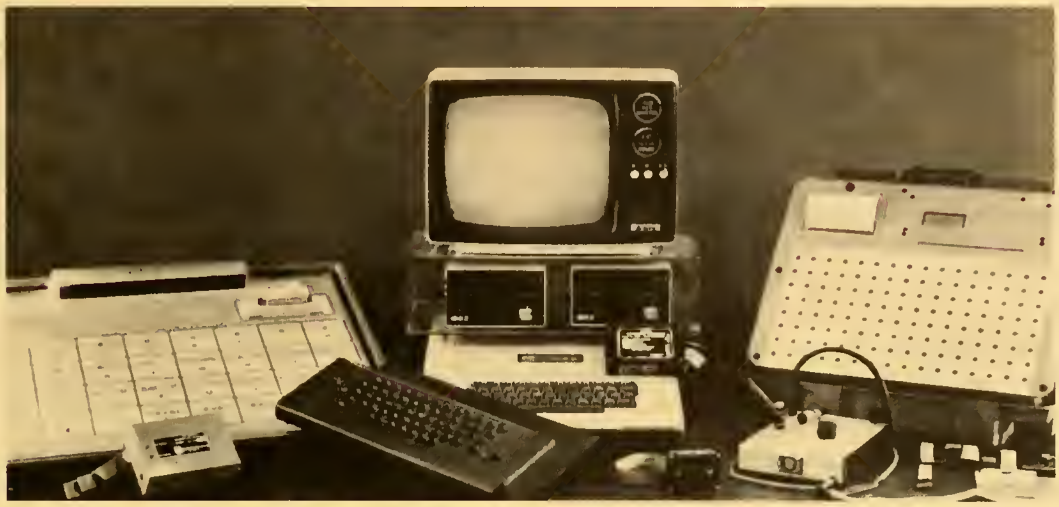

Figure 7. A variety of complex augmentative communication systems (Prentke Romich Company).

Summary

The need for augmentative communication systems is very real and the need is being met. In the past decade, remarkable innovation has occurred in the development of a wide variety of systems. The speechless person with both ability and motivation can learn to communicate again.

Acknowledgments

I appreciate the help of Edward B. Mastin, Medical Photographer, Duke University Medical Center, and Rick Black, Sales Representative for Prentke Romich Company.

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9. Kraat A, Sitver M: *Features of Commercially Available Communication Aids.* Shreve, OH: Prentke Romich Company, 1983.

Appendices

Special Publications

Communication Outlook: A Publication of the International Society for Augmentative and Alternative Communication (ISAAC). Artificial Language Laboratory, Computer Science Department, Michigan State University, East Lansing, MI 48824-1042. (Annual dues and 4 issues of magazine: $12.00.)

Features of Commercially Available Communication Aids. Prentke Romich Company, 8769 Township Road 513, Shreve, OH 44676. (Send $1.00 for chart.)

Manufacturers and Names of Augmentative Communication Systems

Abbey Medical, 8004 Westchester Pike, Upper Darby, PA 19082. ("PMV")

American Communications Corp., 180 Roberts St., East Hartford, CT 06108. ("Am-Com I")

Communications Research Corp., 1720 130th Ave., N.E., Bellevue, WA 98005. ("Omni Communicator, Model 1" and "Omni Communicator, Model 2")

Computers for the Physically Handicapped, 7602 Talbert Ave., Huntington Beach, CA 92647. ("TIM")

C-Phone, 553 Wolfner, Fentin, MI 63026. ("Miniphone" and "Pocket Phone II")

Educational Microcomputer Systems, 1 Clear Spring, Irvine, CA 92715. ("Communi-Mote")

J. A. Preston Corp., 60 Page Rd., Clifton, NJ 07012. ("Scan 100 Communicator" and "Scan 40 Communicator")

Krown Research, Inc., 6300 Arizona Circle, Los Angeles, CA 90045. ("Porta-printer Plus")

Micro Communication Devices, 12388 Priscilla Lane, Los Altos Hills, CA 94022. ("Video-Com II")

N.A.P Consumer Electronics Corp., 159 E. Union Ave., East Rutherford, NJ 07073. ("Odyssey")

Phonic Ear, Inc., 250 Camino Alto, Mill Valley, CA 94941. ("Handivoice 110," "Handivoice 120," "Vois 130," "Vois 140")

Plantronics, Inc., 350 Dell Ave., Campbell, CA 95008. ("Vu-Phone")

Possum, Inc., 82 Birch Ave., Little Silver, NJ 07739. ("Possum 16," "Possum Communicator 100," "Possum Listen & Learn," "Possum Typewriter System")

Prentke Romich Company, 8769 Township Rd. 513, Shreve, OH 44676. ("Expanded Keyboard Memowriter," "Express 3," "Autocom," "Vera-scan")

Scitronics, Inc., 523 So. Clewell St., P.O. Box 5344, Bethlehem, PA 18105. ("Form-A-Phrase")

Sharp Electronics Corp., 9 Sharp Plaza, Paramus, NJ 07652 ("Sharp Memowriter" Models 7001 & 7100)

Shea Products, Inc., P.O. Box 184, Clawson, MI 48017 ("Special Friend")

Specialized Systems, Inc., 11339 Sorrento Valley Rd., San Diego, CA 92121. ("SSI 100," "SSI 220," "SSI 240")

Telegraphics, P.O. Box 1061, Carrollton, TX 75006. ("Scan & Spell")

Telesensory Systems, Inc., 455 N. Bernardo, Mountain View, CA 94043. ("Canon Communicator" and "Mark 2")

Texas Instruments, P.O. Box 10508, Lubbock, TX 79408 ("Language Tutor," "Speak 'N Spell," "Vocaid")

Ultratec, Inc., P.O. Box 4062, Madison, WI 53711. ("Superphone")

Words +, Inc., 622 S. Fair Oaks, Sunnyvale, CA 94086 ("Words Plus Living Center")

ZYGO Industries, Inc., Box 1008, Portland, OR 97207. ("ZYGO 16C" and "ZYGO Model 100")

Endoscopy, A Growing Part of Medicine

Charles M. Mansbach, II, M.D.

GASTROENTEROLOGISTS are doctors who are interested in the diagnosis and treatment of disorders of the esophagus, stomach, intestinal tract, colon, liver, and pancreas. This subspecialty of internal medicine had few practitioners until beginning in the late 1960s when the widespread use of flexible endoscopes began. Since that time, growth of this subspecialty has been nothing short of phenomenal mainly due to the subject matter of this article: endoscopy. To understand what differences endoscopy has made to the practice of medicine, we first must explore what an endoscope is and what it can do.

An endoscope is an instrument that literally "sees in." That is, an endoscope is any instrument by which a doctor can look inside any part of the body. We will take this to mean any part of the intestinal tract. As we examine the history of the development of this instrument, it will be rapidly understood why there were relatively few practitioners of this art up until the present day.

Doctors first developed an instrument in the middle part of the 19th century which could look inside the stomach. Dr. Kussmoul, who invented this instrument, was inspired by a sword swallower he happened to see on a Sunday stroll. The amount of light able to be generated by the alcohol-turpentine lamps in use at that time, however, was not great enough to make this instrument worthwhile. In 1906, electric light bulbs were miniaturized and instruments were developed that took advantage of this fact. This culminated in 1932 in the development of an instrument that had both a stiff and a flexible portion. The flexible portion, which was in the stomach, could be moved so that a reasonable portion of the stomach wall could be visualized.

In 1958 the first totally flexible gastroscope was invented. This was the first instrument that did not require the sword-swallowing technique. What allowed the development of the totally flexible instrument was the use of fiberoptics. In these fiberoptic instruments, thousands of tiny glass rods are tied together into what is termed a fiber bundle. These glass rods are each specially coated so that they pick up only a small fraction of the total scene that is viewed. All the fiber bundles together then allow the entire scene to be visualized as a whole. Without this special coating, each fiber bundle might see the entire scene and to the viewer it would appear as thousands of miniature views of the same thing. Modern day fiberoptics has enabled the successor instruments to the first flexible gastroscope to have excellent optical quality. Subsequent to the development of flexible endoscopes for examination of the upper intestinal tract, instruments based on the same principles were developed for study of the colon.

The endoscopes that we will discuss have two general purposes. The first function is diagnosis, which we will explore first, and the second is treatment, which is becoming a factor of greater and greater importance in endoscopic usage.

Diagnosis

Esophagogastro-duodenoscopy: What do doctors see when they look into the intestinal tract and why do they wish to do it? In terms of upper intestinal disease, the doctor performing the endoscopy (the endoscopist) is able to examine the esophagus, the stomach, and the first portion of the small intestine called the duodenum. These areas are the site of large numbers of patient complaints including peptic ulcer disease, heartburn, and intestinal bleeding. Using the endoscope the doctor can evaluate the extent and severity of esophagitis (inflammation of the esophagus) which usually results from the reflux of gastric acid up into the esophagus. Complaints of food sticking in the esophagus after being swallowed are routinely investigated by endoscopy to rule out the presence of an esophageal tumor or stricturing of the esophagus (narrowing of its inner diameter) resulting from the constant reflux of gastric acid. Endoscopy is also useful in seeing whether or not the patient has enlarged veins in the esophagus due to severe liver disease.

In the stomach and first portions of the duodenum, doctors are usually looking for the presence of ulcers. If an ulcer is found in the stomach, the question of its cancerous nature is always raised. To rule out cancer, the ulcer can be biopsied directly through the endoscope and specimens can be obtained for cytologic examination. Ulcers usually appear as a yellow area in the normally pink-red background of the gastric surface, or mucosa. Sometimes the ulcer beds are filled with debris; sometimes, especially after bleeding, clots or black scabs appear at the surface of the ulcer.

At other times, no ulcer is seen but, rather, erosions of the stomach lining or a generalized inflammatory response called gastritis. Gastritis usually appears as inflammation does elsewhere as reddened raw-appearing mucosa. These types of lesions are often caused by alcohol or drugs such as aspirin.

Occasionally polyps of the stomach are found. They are biopsied and

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cytologic specimens are obtained to rule out as well as possible their cancerous nature. Ofttimes, they may be safely removed through the endoscope as will be discussed later.

Patients who have had previous gastric surgery, especially those in whom part of the intestine has been brought up to an opening made in the stomach, often complain of either pain or bleeding. In this instance, the endoscope is an invaluable tool to examine for the presence of an ulcer in the opening between stomach and intestine made by the operation. Sometimes patients complain of vomiting although the vomited food has never left the stomach. In such cases, doctors wish to examine the valve, called the pylorus, which is between the stomach and the first part of the duodenum, where narrowing may occur due to longstanding peptic ulcer disease or where a tumor might have obstructed the outflow of gastric contents.

Endoscopic retrograde choledocopancreatography: A different type of endoscope is used for evaluating the common bile duct and pancreatic duct. These ducts are the channels whereby bile and pancreatic juice, respectively, gain access to the intestine. In this case, the endoscope that is used has its viewing part on the side rather than in front and is equipped with a special channel which allows the introduction of a long catheter. When the endoscope is placed opposite the mound-like opening of the common bile and pancreatic ducts in the first portion of the small intestine, a catheter is advanced into these small ducts. X-ray-visible dye is injected through the catheter, first into the pancreatic and subsequently into the common bile duct. By looking at the image of the ducts on x-ray, doctors can pick out stones in either the pancreatic or biliary ducts, patterns suggestive of tumors involving these organs, or other diseases such as chronic pancreatitis and cysts of the pancreas.

Colonoscopy: Colonoscopy is the examination of the colon by the use of a similar instrument. In order to examine the colon the patient is given a special salt solution which causes evacuation of all fecal material from the colon. The colonoscope is then inserted into the rectum and the colon is examined to the cecum where the colon proper begins. In some cases, the last portion of the small intestine may be entered via the cecum. In examining the colon, doctors are mainly concerned with the presence or absence of colonic cancer or polyps. Other reasons for doing colonoscopy include investigation for intestinal bleeding or evaluation of the extent of inflammatory bowel disease such as ulcerative colitis or Crohn's disease of the colon.

Treatment

Endoscopy is entering a new phase in which treatment is provided in selected cases after a diagnosis is made. Each modality of treatment will be considered separately.

Sclerotherapy: Sclerotherapy is used to prevent rebleeding from enlarged veins (varices) in the distal esophagus in patients who have been shown to bleed from these vessels. Large amounts of blood are often lost when bleeding occurs in this situation. These enlarged veins usually arise in patients who have cirrhosis of the liver and they form an escape route for blood that is unable to pass through the liver. The physician uses an endoscope to visualize the varix and injects it with the sclerosing agent which obliterates the vein. This is repeated until two to three veins have been injected. The patient is then brought back weekly for repeated injections until all veins have been successfully injected and no varices are visible.

Polypectomy: Polypectomy or removal of polyps is usually performed via the colonoscope because most polyps of the intestinal tract are found in the colon. The doctor inserts the colonoscope to the level of the polyp. A snare wire is inserted through the colonoscope and it encircles the base of the polyp. An electrocautery-coagulation current is passed through the wire which separates the stalk of the polyp from the colonic wall. The polyp is then retrieved for pathologic examination. Multiple polyps can be removed in this fashion at one time. These are important procedures because removal of the polyps lessens the likelihood of colonic cancer. Polyps of the stomach can also be removed in a similar fashion.

The advantage of this type of procedure is that patients who used to require a surgical operation for polyp removal can now have this performed essentially as an outpatient procedure or one that requires only a one-night stay in the hospital.

Sphincterotomy: After gallbladder removal, stones are occasionally found in the biliary system. These stones may give rise to major symptoms and therefore must be removed. In the past, this has required a surgical procedure with an exploration of the common bile duct. Usually a T-tube (a tube shaped as a T) would be placed in the duct and bile would drain through the tube to the outside for several weeks after the procedure. With sphincterotomy, however, no operation is required and usually no tubes are left in the duct after the procedure. To perform the procedure, doctors visualize the sphincter or the outlet of the common bile duct and pancreatic duct into the duodenum. The sphincter, which normally has a small opening, is then cut to a precise degree which enlarges the opening for both bile and pancreatic juice to flow into the small intestine. The opening is made large enough (usually 1.2-1.5 cm) so that stones may be extracted from the duct using another catheter which has a balloon on it. The catheter is passed so that the balloon is inflated behind the stone and the stone is then retrieved from the duct by pulling the balloon out through the newly enlarged sphincter. This procedure may also be performed on those patients who are debilitated or who are quite aged if they have symptomatic stones in the common bile duct even if their gallbladder is present. In this case, it is hoped that an operation to remove the gallbladder would not be required.

Laser Therapy: Gastroenterologists have explored ways to use lasers in the treatment of gastrointestinal disorders. For gastroenterologists, lasers are a means of administering heat to a precise area of the lining of the intestinal tract. Different types of lasers have different usages depending upon how deep the heat must penetrate into the tissue. The laser most commonly used by endoscopists is the Ng:YAG which gives off a greenish colored light. Light guide wires have been developed that can be inserted through the endoscope and reach the area to be treated. When the laser is turned on, the area of the intestinal tract that is being lased undergoes a sequence of reactions, the end result of which is char or vaporization. Care must be taken so that a through-and-through burn of the intestinal tract is not produced. This can be done using carefully calibrated machinery for standardized amounts of time. As laser therapy progresses, the endoscopist watches the results through the endoscope. His best guide is to follow the known sequence of events that occurs under laser therapy and to stop when he feels that enough treatment has been given.

Another use for laser therapy is to coagulate small arteries just below the surface of either the colon or the stomach. These appear as a tangled web of vessels or as a bright red dot occasionally with single branches emanating from the central focus. These so-called telangiectosias may bleed silently, especially in older people. Laser therapy can be applied to these vessels and adequate coagulation accomplished so that bleeding does not recur from that site. Using a different type of instrument, electracautery units can accomplish the same thing and stop bleeding.

An additional palliative therapeutic use of the laser is the obliteration of the portion of a cancer obstructing the esophagus. In this situation, the obstructing tumor is progressively vaporized by the laser heat until there is no obstructing tumor left within the lumen of the esophagus. An Argon laser is ofttimes used for this type of work.

Relief of Impacted Food Substances: Occasionally food, usually a piece of meat that has been poorly chewed, gets stuck in the lower portion of the esophagus, almost always in association with narrowing of the esophagus. This situation produces an intensely uncomfortable sensation in which further food or fluid cannot be swallowed without vomiting. The physician passes the endoscope to the site of obstruction and the food causing the problem is visualized. The preferred method is to attempt to push the food into the stomach which is done while looking to be certain that the opening in the esophagus is large enough to permit passage of the endoscope and the impacted food. Alternatively, the food can be picked apart piecemeal by small forceps. Occasionally, it is necessary to extract the impacted food by gripping it with a forceps and removing the endoscope with the forceps and the food.

Endoscopy has grown from a simple adjunct to the diagnosis of gastrointestinal diseases to a powerful therapeutic tool. Undoubtedly, as the years progress, more and more uses will be devised for it. At present it remains an extremely useful tool in the armamentarium of physicians. Diagnoses which heretofore had been only educated guesses can now be shown to be accurate or false. Treatment can be administered in a wide variety of areas, often avoiding the need for a formal surgical procedure. For these reasons, endoscopy is playing a major role in the practice of medicine and will undoubtedly play an even greater role in the future.

Acne and Accutane

Claude S. Burton, M.D., Russell W. Eyre, M.D., and J. Lamar Callaway, M.D.

Socially crippled, cosmetically disfigured, and financially exhausted in search of a cure, acne sufferers take heart. Our recent experience with Accutane (a recently released oral treatment for acne) suggests the once familiar "ice-pick" scarring of acne is now an endangered species. Accutane, a synthetic form of the naturally occurring vitamin A byproduct Isotretinoin was first marketed for acne in the U.S. in September 1982. Accutane produces a permanent remission of acne in the vast majority of patients following a single 16-20 week course of therapy. Therapy costs less than we anticipated in our article in this *Journal* in May 1983, yet remains a burden for many. Tablets to complete the recommended 16-20 week course of therapy cost $200-$400. The necessary doctor visits and lab studies add an additional $150 to the cost. Still, Accutane is a bargain if one considers the long-term cost of alternative, less effective therapies.

The price one pays for marvelous results includes many uncomfortable side effects. Accutane is a potent inhibitor of oil production essential for lubrication of the skin and mucous membranes. Everyone experiences chapped lips that may crack and bleed. Dry eyes may produce conjunctivitis and vaginal dryness may interfere with sexual intercourse. Dry nasal mucous membranes may lead to nosebleeds. If the skin dries to the point of cracking, itching and rash may appear. We ask all patients to use lip moisturizers from the start of therapy. Artificial tears and moisturizers for skin and mucous membranes are recommended as necessary. Fortunately, since Accutane is not stored in the body, these side effects vanish when therapy ceases.

The ideal therapeutic dose is close to the toxic dose. Therapy must be individualized. Adjustments are often necessary during a 16-20 week course. In addition to the drying effects, there are other side effects too numerous to list. Thinning of the hair, increased sun sensitivity, musculoskeletal aches and pains, irregular wound healing, and fatigue are noted frequently. These are rarely serious, resolve spontaneously after cessation of therapy, and respond to symptomatic treatment. Two more serious associations are bowel inflammation and cataract formation noted in a few patients. As with any drug, patients are advised to stop therapy and consult their physician if unusual symptoms appear. Long-term therapy is more hazardous, produces permanent bony and ocular changes, and is not indicated for acne. If a second course must be given, a holiday between courses is advisable. Frequently patients continue to note improvement long after stopping the drug.

Oil production returns, acne does not. What other actions of this drug are responsible for the sustained improvement? Accutane has potent, enigmatic influences on cellular development. Malignant nerve cells harvested from cancer patients transform to normal cells if grown in the presence of this drug. Trials in cancer patients are in progress. Such observations suggest a developmental role for Accutane in the skin of acne sufferers. For instance, a change in cells at the neck of oil glands would prevent blocked oil glands — the earliest lesion in acne. Experience has shown that lower doses of Accutane will inhibit oil production and clear acne temporarily. Higher doses are associated with sustained improvement in spite of the return of oil production. Theoretically, the higher doses induce permanent changes in the skin of acne sufferers.

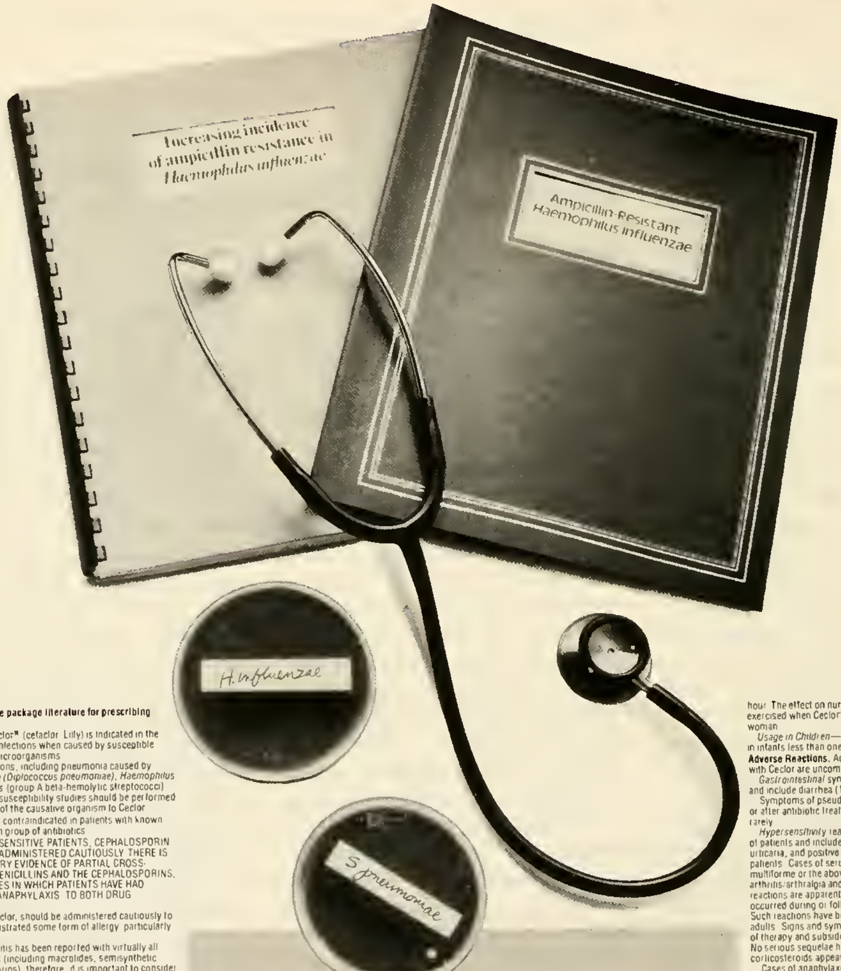
It is the potent influence on developing cells that scares us the most. Any woman who becomes pregnant while taking the drug or is pregnant when therapy is started will likely produce a deformed child. Few agents are as poisonous to the developing fetus. Extreme caution to avoid the use of Accutane during the period of conception or gestation is indicated. Despite these warnings, numerous horribly deformed children have been produced. On the other hand, once therapy is complete, childbearing is safe. Accutane is rapidly eliminated from the body. The manufacturer recommends waiting one menstrual cycle after therapy before attempting conception.

For some, the therapy has arrived too late. The fire department can quench a burning roof with water but all the water in the world will not reshingle the roof. The same is true in acne. This drug will arrest the process but do nothing for the scarring already present. Our goal is to treat patients before permanent damage has been done. We finally have an agent that produces consistently marvelous and permanent results.

We wish to emphasize again that this therapy for a common disease requires the close supervision of a doctor. You are at great risk if you acquire a quantity of Accutane and treat yourself. Don't do it!

From the Department of Medicine, Duke University Medical Center, Durham 27710.

An added complication... in the treatment of bacterial bronchitis*



Brief Summary Consult the package literature for prescribing information

Indications and Usage Ceclor™ (cefaclor Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae), Haemophilus influenzae* and *S pyogenes* (group A beta-hemolytic streptococci)

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor

Contraindication. Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics

Warnings IN PENICILLIN SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS INCLUDING ANAPHYLAXIS TO BOTH DRUG CLASSES

Antibiotics including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy particularly to drugs

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins), therefore it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics Such colitis may range in severity from mild to life-threatening

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid electrolyte, and protein supplementation When the colitis does not improve after the drug has been discontinued, or when it is severe oral vancomycin is the drug of choice for antibiotic associated pseudomembranous colitis produced by *C difficile* Other causes of colitis should be ruled out

Precautions *General Precautions*—If an allergic reaction to Ceclor occurs the drug should be discontinued and, if necessary the patient should be treated with appropriate agents, e g pressor amines, antihistamines, or corticosteroids

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms Careful observation of the patient is essential If superinfection occurs during therapy, appropriate measures should be taken

Positive direct Coombs tests have been reported during treatment with the cephalosporin antibiotics In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs test may be due to the drug

Ceclor should be administered with caution in the presence of markedly impaired renal function Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended

As a result of administration of Ceclor a false-positive reaction for glucose in the urine may occur This has been observed with Benedict s and Fehling s solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP Lilly)

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease particularly colitis

Usage in Pregnancy—Pregnancy Category B—Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor There are however no adequate and well-controlled studies in pregnant women Because animal reproduction studies are not always predictive of human response this drug should be used during pregnancy only if clearly needed

Nursing Mothers—Small amounts of Ceclor have been detected in mother's milk following administration of single 500 mg doses Average levels were 0 18, 0 20, 0 21 and 0 16 mcg ml at two three four and five hours respectively Trace amounts were detected at one hour The effect on nursing infants is not known Caution should be exercised when Ceclor® (cefaclor, Lilly) is administered to a nursing woman

Usage in Children—Safety and effectiveness of this product for use in infants less than one month of age have not been established

Adverse Reactions. Adverse effects considered related to therapy with Ceclor are uncommon and are listed below

Gastrointestinal symptoms occur in about 2 5 percent of patients and include diarrhea (1 in 70)

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment Nausea and vomiting have been reported rarely

Hypersensitivity reactions have been reported in about 1 5 percent of patients and include morbilliform eruptions (1 in 100) Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently fever) have been reported These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor Such reactions have been reported more frequently in children than in adults Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy No serious sequelae have been reported Antihistamines and corticosteroids appear to enhance resolution of the syndrome

Cases of anaphylaxis have been reported half of which have occurred in patients with a history of penicillin allergy

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients)

Causal Relationship Uncertain—Transitory abnormalities in clinical laboratory test results have been reported Although they were of uncertain etiology they are listed below to serve as alerting information for the physician

Hepatic—Slight elevations of SGOT, SGPT, or alkaline phosphatase values (1 in 40)

Hematopoietic—Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40)

Renal—Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200)

(061782R)

Some ampicillin-resistant strains of Haemophilus influenzae—a recognized complication of bacterial bronchitis*—are sensitive to treatment with Ceclor.[1-6]

In clinical trials, patients with bacterial bronchitis due to susceptible strains of Streptococcus pneumoniae, H. influenzae, S. pyogenes (group A beta-hemolytic streptococci), or multiple organisms achieved a satisfactory clinical response with Ceclor.[7]

Ceclor®
cefaclor

Pulvules®, 250 and 500 mg

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*Many authorities attribute acute infectious exacerbation of chronic bronchitis to either *S pneumoniae* or *H influenzae* [8]

Note Ceclor is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever See prescribing information

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PHARMACOTHERAPY

Drug Therapy of Systemic Fungal Infections, Part I

Mark Gross, Pharm.D.

AS antibiotic and antineoplastic therapies have become more potent, serious fungal infections have increased in incidence.[1] Although newer antibiotics more effectively eliminate competitive forces, fungi may proliferate unchecked, resulting in disseminated infections. Multisystem mycoses are infrequent in the normal host and the pathogen is usually contained at the site of entry. In hosts with immune function altered by other drugs (e.g., corticosteroids, cancer chemotherapy) or diseases (e.g., AIDS, congenital immunodeficiencies) and who may be receiving numerous antibacterials, systemic fungal infections often lead to morbid or fatal outcomes. Common fungal infections include candidiasis, blastomycosis, histoplasmosis, coccidioidomycosis, and cryptococcosis. Treatment is further complicated by the tendency of more potent antifungals to demonstrate increasingly severe side effects. Effective antimycotic therapy may therefore be limited by iatrogenic complications.

This review is intended to discuss the more widely used antifungals with respect to their clinical indications, pharmacology, toxicities, and pharmacokinetics.

Ketoconazole (Nizoral)

Ketoconazole, an imidazole derivative, exerts its antifungal effects by disrupting ergosterol synthesis and thereby inhibiting growth of the cell membrane.[2] The imidazoles are generally considered fungistatic compounds, but at higher concentrations cidal actions involving RNA have been observed.[3, 4] Ketoconazole is FDA-approved for the treatment of candidiasis, coccidioidomycosis, histoplasmosis, paracoccidioidomycosis, blastomycosis, and chromomycosis. The drug's major advantage over amphotericin B is that it can be used orally and that it is less toxic.[11] Unfortunately, many clinical studies of ketoconazole have involved non-controlled groups or case reports, making an evaluation of its clinical efficacy difficult at the present time.

Dismukes et al, in a non-controlled, non-randomized study, treated 52 patients with 100-600 mg/day of ketoconazole for blastomycosis, non-meningeal coccidioidomycosis, sporotrichosis, histoplasmosis and cryptococcosis.[5] Doses were increased according to the severity of the infection, and treatment lasted from 13 days to 12 months. Overall, 52% of patients were judged cured or improved while 48% either relapsed, failed to improve, or died of other complications. Those with histoplasmosis showed a superior response followed by those with non-meningeal coccidioidomycosis, cryptococcosis, sporotrichosis, and finally blastomycosis. Varying the daily dose could not be correlated with outcome but prolonged therapy greater than six months did prove beneficial. Although positive effects were demonstrated, this study has been criticized for the relatively short and variable duration of treatment, failure to include controls, and poor criteria for clinical cure.[6] Before a mycosis can be assumed cured, a patient should be monitored for as long as two years for histoplasmosis and cryptococcosis and five years for coccidioidomycosis.[6] It has also been suggested that a greater therapeutic outcome could be achieved if ketoconazole were administered following amphotericin B induced remission.[6]

A preliminary study suggests that high doses of ketoconazole may effectively control CNS infections of coccidioidomycosis or histoplasmosis.[7] Six patients, four of whom received concurrent amphotericin B, also took high doses of ketoconazole (600-1200 mg/day) for indefinite periods. Two patients ceased amphotericin B therapy while showing improving symptoms or no clinical disease. Although ketoconazole penetration into the CNS is minimal (1-5% of serum levels), the data demonstrate that this regimen may have a therapeutic effect.[7] Unfortunately the fungistatic nature of the drug will probably necessitate life-long continuation to assure suppression of the disease. However, when compared with the possible complications of amphotericin B, this may be an acceptable alternative.

Ketoconazole is the drug of choice for chronic mucocutaneous candidiasis.[3] Peterson et al, using 100-600 mg/day of ketoconazole, documented favorable responses in six of six patients and later in five of six from a previously placebo-controlled group.[8] Treatment lasted for at least six months in all patients. Mucosal improvement was often noticed before cutaneous improvement.

Peak plasma levels of ketoconazole occur 2-4 hours after oral dosing with a maximum of 1.6-6.9 mcg/ml in the serum after a 200 mg dose.[9] Normal doses begin at 200 mg once daily and may be increased up to 600 mg/day. Better GI absorption occurs in the presence of food and acid.[10] Absorption is reduced when the drug is consumed with antacids, cimetidine, or ranitidine.[10] The drug is highly protein-bound and only negligible amounts penetrate the CSF.[11] Ketoconazole is primarily excreted as an inactive metabolite in the feces and less than 5% of the drug is excreted unchanged in the urine.[12] Renal failure would not be expected to result in delayed elimination or toxicity and it is not yet clear whether liver disease would also affect ketoconazole elimination. Case reports of patients receiving ketoconazole with moderately severe liver function

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were not associated with drug accumulation.[13]

The most serious toxic reaction to ketoconazole is hepatotoxicity which may occur in up to 5% of patients and results in elevated SGOT levels.[3] Such toxicity, however, does not appear to be dose-related.[3] It is recommended that the drug should be discontinued if any signs of symptomatic liver disease occur and liver function should be checked periodically.[3] Ketoconazole may cause a dose-related depression of serum cortisol and testosterone levels, although the clinical significance of these changes is minimal.[3] Other side effects include nausea and vomiting (3%), abdominal pain (1.3%), pruritis (1.7%), headache (0.9%), and gynecomastia (3-8%).[11]

Presently, no conclusions relative to ketoconazole's effectiveness in systemic mycoses can be made due to the paucity of large, controlled, randomized trials. It is apparent, however, that the drug may effectively suppress a number of serious mycoses such as mucocutaneous candidiasis, histoplasmosis, and coccidioidomycosis. The drug may be especially useful as a suppressive agent following fungicidal therapy with amphotericin B in susceptible infections, but this regimen has not been tested. Long durations of treatment often greater than 6 months will be necessary in most infections due to the fungistatic nature of the drug. In candidiasis, the effectiveness of ketoconazole remains to be determined but it may have potential benefit for this increasingly common infection.

Amphotericin B (Fungizone)

Amphotericin B is currently the most effective antifungal agent available yet also the most toxic. Despite its severe side effects, it is the standard by which other systemic antifungals are compared. The mixed hydrophobic and hydrophilic properties of ths fungicidal drug allow it to bind to fungal (or protozoal) ergosterol, the fungal equivalent of cholesterol, disrupting membrane integrity and intracellular electrolyte balances.[3] Besides its direct antifungal effects, amphotericin B may also augment the host's immunologic mechanisms.[43]

Amphotericin B is often used in the treatment of candidal infections in immunocompromised or post-surgical patients. Low doses of amphotericin B may be effective in some of these infections, thus avoiding the nephrotoxicity common to higher doses. Medoff et al. treated fourteen patients with candidal pneumonia, fungemia, urinary tract infections, esophagitis, and vaginitis using total doses that ranged from 12 to 355 mg over four to ten days.[15] Infections were eradicated in 12 patients and the authors often noted improvement after one dose. Excluded were patients with candidal meningitis or endocarditis because these diseases require higher doses and prolonged treatment. However, no prospective study has defined the appropriate dose or duration for disseminated candidiasis, particularly in the neutropenic patient, where longer courses of therapy may be needed.

Cryptococcal meningitis is associated with a high failure rate of treatment, especially in immunosuppressed patients. Bennett et al. compared the effectiveness of a ten week course of amphotericin B alone with a six week course of amphotericin B and flucytosine in 51 patients with cryptococcal meningitis.[16] Although the study was designed only to determine whether the combination was equivalent to amphotericin B alone, the authors concluded that the combination was superior to amphotericin B alone because of the shorter treatment interval, more rapid CNS sterilization, and fewer deaths in patients receiving both drugs. However, flucytosine has its own potential toxicity and, in fact, with either regimen only approximately two-thirds of patients were successfully treated. A recent case report successfully used equivalent doses of amphotericin B and flucytosine to treat a 47-year-old man with a candidal lung abscess, eradicating the abscess after 26 days of combination therapy.[17] The authors suggest that this combination is synergistic against candida, but there is no evidence that the infection would not have been eradicated as rapidly using amphotericin B alone. Furthermore, there are no prospective studies to suggest that the combination would be more effective than single agents for yeast (i.e., candida) infections.

Fungal resistance to amphotericin B has not been frequently documented although it may occur in cases where high doses of the drug have failed to achieve a cure. Pappagianis et al documented acquired amphotericin B resistance in a rare form of candida *(C. lusitaniae)* that demonstrated MICs of 0.31 mcg/ml before amphotericin B treatment and 30 mcg/ml following amphotericin in a single case of fatal candidemia in a leukemic male.[18] It is presently conceded that *in vitro* resistance to amphotericin B is not clinically important. However, widespread use of amphotericin B in severely immunocompromised hosts may lead to production of virulent mutants and surveillance must therefore continue.

Rifampin, an antibacterial that inhibits RNA synthesis, has been studied for possible antifungal synergy with amphotericin B *in vitro* and in animals with mixed results. Medoff found rifampin to be synergistic *in vitro* with amphotericin B against strains of *Histoplasma, Saccharomyces*, and *Aspergillus* and the combination appeared to prolong survival and decrease morbidity in mice.[19] However Ernst et al failed to duplicate this trend in experimental candidal infections in corticosteroid-treated guinea pigs.[20] Presently there is no definitive evidence indicating that rifampin and amphotericin B should be used together in a clinical setting.

The distribution of amphotericin B follows a three-compartment model with a volume of distribution of 5 L/kg.[21] More than 90% of the drug is protein bound and thus poorly dialyzable.[22] Less than 5% of the drug is absorbed after oral administration.[3] Peak serum levels approximate 2 mcg/ml with a distribution half-life of 24-48 hr and an excretion half-life of 10-12 days.[21] A single intravenous dose may provide therapeutic concentrations in the bile, urine, or stool for up to one week.[3] Although renal failure may not affect amphotericin B levels, it may predispose the kidneys to nephrotoxicity.[23]

The major route of elimination still remains unclear. Craven et al found that the bile and urine may account for 40% of eliminated amphotericin B. Detectable levels of the drug have been found in kidney tissue of a patient 12 months after a 21 gram cumulative dose was completed.[25] Therefore a large percentage of the drug may undergo either long term tissue sequestration or elimination via an as yet undetermined metabolic pathway.

Because of the variation in pathology, fungal susceptibility, and patient sensitivity, the dose of amphotericin B may vary from patient to patient. The most serious mycoses will require a daily dose of 0.3-1.0 mg/kg, while those with less severe infections may be adequately treated with doses as small as 15 mg/d. Initially a test dose of 1 mg over 2 hr should be given while the patient is observed for an anaphylactic reaction. Ten additional milligrams may be administered if no reaction develops, but if the patient is acutely ill with infections such as disseminated aspergillosis as high as 0.3-0.5 mg/kg may be given. The dose may be increased by increments of 5-10 mg per day until a full daily dose has been achieved. Patients who are intolerant to daily doses may receive the drug on alternate days without compromising the antifungal effect.[26] The risk of nephrotoxicity, however, is not reduced with alternate-day treatment.[26]

Intrathecal administration of amphotericin B usually begins with 0.1 mg, increasing in 0.1 mg intervals to 0.5 mg per week.[26] Unfortunately this procedure is fraught with risks such as subarachnoid hemorrhage, severe intractable headaches, and seizures and should only be undertaken as a last resort.

The most widely recognized toxic manifestation of this drug is nephrotoxicity, and may be due to a number of mechanisms. This occurs by drug-induced decreases in glomerular filtration rate, renal tubular acidosis, decreased serum potassium and hypomagnesemia.[27] Concurrent administration of aminoglycosides may hasten renal toxicity.[28] A recent report suggests that patients may be predisposed to this nephrotoxicity if they are sodium depleted secondary to diuretics, low sodium diets, anorexia, or vomiting.[29] In five patients sodium loading was associated with improved renal function which permitted amphotericin B therapy to be continued to the completion of antifungal therapy. It is not known whether these findings imply that a high salt intake before treatment will prevent nephrotoxicity.

Other toxic reactions include normocytic, normochromic anemia, which may occur due to a reduction in erythropoiesis, and after several weeks of amphotericin B, hematocrit levels are expected to be in the 25-30% range.[30] Thrombocytopenia associated with amphotericin B has been reported in a leukemic male; it resolved when the drug was discontinued and recurred upon rechallenge. To minimize thrombophlebitis, amphotericin B infusions are prepared with a phosphate buffer to raise the pH above 6.5. Hydrocortisone (20-50 mg per liter) and heparin (1 unit/ml) also may minimize irritation. To prevent fevers and chills during administration, the patient may be premedicated with diphenhydramine 25-50 mg, acetaminophen 300-600 mg, or meperidine 25-75 mg. The drug must be prepared in saline-free solutions in order to avoid inactivation. Generally the drug is given over 6-8 hours. Some patients may tolerate faster infusions, although there is much individual variability.

Part II will appear in the
September 1984 issue
of the NCMJ.

References available from the NCMJ editorial office.

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EDITORIAL

A View from the National Academy of Sciences: Science and Creationism

Frank Press

THE National Academy of Sciences with the support of a North Carolina foundation (Mary Reynolds Babcock) has published an excellent paper which should be in the hands of all the members of school boards and school committees. It should be made widely available to all non-science teachers who may need accurate information about evolution.

I quote the Preface by Frank Press in its entirety. Press is the president of the National Academy of Sciences.

"Before you begin to read this discussion of science and creationism, please take a careful look at the front and back covers of this booklet. The front cover depicts the world as we know it to be today. The back cover illustrates the world as people believed it to be in the days before Columbus sailed to the New World. Both views have a place in our lives — but one belongs in the world as we have come to know it and one belongs in history. Both views, by the way, are the products of science. How then can the two views be so different? The answer lies at the very heart of the nature of this system of study we call 'science.'

"In science, everything we observe, measure, or discover must be successfully tested again and again before it is accepted as valid and as factual evidence of what is real. During the application of this scientific method, scientists review their data carefully — and with a healthy skepticism. Most important, the scientific method requires that the fact-seekers remain open-minded, are willing to accept changes indicated by the signposts of evidence. It is easy to see how this approach encourages the acceptance of change, which in turn fosters original thought, new ideas, and new hypotheses, all converging on a better understanding of nature.

"One might think of Columbus's voyage to the New World as a test of the hypothesis that India, which lay to the east, could be reached by sailing westward on a round world. As a result of his exploration and many subsequent observations, including those from voyages into space, we now know that our world actually looks as it is shown on the front cover of this booklet.

"And that is why scientists, such as those of the Council of the National Academy of Sciences who asked that this booklet be prepared, feel that teaching the scientific theory of evolution alongside creationism is inappropriate. Teaching creationism is like asking our children to believe on faith, without recourse to time-tested evidence, that the dimensions of the world are the same as those depicted in maps drawn in the days before Columbus set sail with his three small ships, when we *know* from factual observations that they are really quite different.

"It is false, however, to think that the theory of evolution represents an irreconcilable conflict between religion and science. A great many religious leaders and scientists accept evolution on scientific grounds without relinquishing their belief in religious principles. As stated in a resolution by the Council of the National Academy of Sciences in 1981, however, 'Religion and science are separate and mutually exclusive realms of human thought whose presentation in the same context leads to misunderstanding of both scientific theory and religious belief.'

"The theory of evolution has successfully withstood the tests of science many, many times. Thousands of geologists, paleontologists, biologists, chemists, and physicists have gathered evidence in support of evolution as a fundamental process of nature. Our understanding of evolution has been refined over the years, and indeed its details are still undergoing testing and evaluation. For example, some scientists currently debate competing ideas about the rate at which evolution occurred. One group believes that evolution proceeded in small, progressive stages evenly spread throughout the billions of years of geological time; another group believes that there were alternating periods of relatively rapid and slow changes throughout time.

"Creationists sometimes cite this debate as evidence for disagreement about evolution among scientists; some even suggest that scientists who advocate the latter hypothesis are actually supporting a process similar to that of creationism. What these creationists fail to understand, however, is that neither scientific school of evolutionary thought questions the scientific evidence that evolution took place over billions of years. Rather, the debate centers on only the finer details of *how* it took place.

"Debate among scientists is expected. And the products of such debate over the years have been truly astonishing. Scientific debate influenced the planning of Columbus's voyage and, more recently, the explorations of space. But debate does not mean resurrecting old theories that have long been invalidated by observations and experiments. Theories that are supported by evidence, and which survive the rigorous testing of the scientific method, are passed on to future generations. Examples are the germ theory of disease; the theory of gravity, which controls the movement of planets; and the theory of evolution. Those that are discounted by the evidence, and which fail by the scientific method, are of interest only to the historians of science.

"In a nation whose people depend on scientific progress for their health, economic gains, and national security, it is of utmost importance that our students understand science as a system of study, so that by building on past achievements they can maintain the pace of scientific progress and ensure the continued emergence of results that can benefit mankind."

Copies of *Science and Creationism* are available as follows:

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10 or more	$1.75 each

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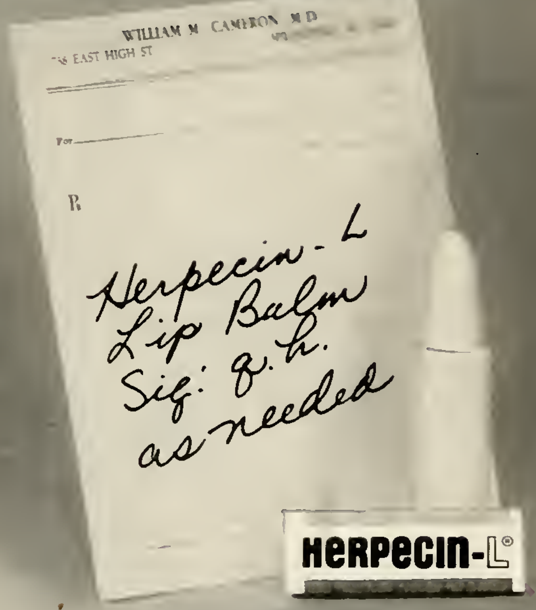

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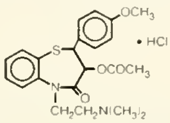
References:
1. Strauss WE, McIntyre KM, Parisi AF, et al: Safety and efficacy of diltiazem hydrochloride for the treatment of stable angina pectoris: Report of a cooperative clinical trial. Am J Cardiol 49:560-566, 1982.
2. Pool PE, Seagren SC, Bonanno JA, et al: The treatment of exercise-inducible chronic stable angina with diltiazem: Effect on treadmill exercise. Chest 78 (July suppl):234-238, 1980.

PROFESSIONAL USE INFORMATION

cardizem®
(diltiazem HCl)
30 mg and 60 mg tablets

DESCRIPTION

CARDIZEM® (diltiazem hydrochloride) is a calcium ion influx inhibitor (slow channel blocker or calcium antagonist). Chemically, diltiazem hydrochloride is 1,5-Benzothiazepin-4(5H)one,3-(acetyloxy)-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-, monohydrochloride,(+)-cis-. The chemical structure is:



Diltiazem hydrochloride is a white to off-white crystalline powder with a bitter taste. It is soluble in water, methanol, and chloroform. It has a molecular weight of 450.98. Each tablet of CARDIZEM contains either 30 mg or 60 mg diltiazem hydrochloride for oral administration.

CLINICAL PHARMACOLOGY

The therapeutic benefits achieved with CARDIZEM are believed to be related to its ability to inhibit the influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle.

Mechanisms of Action. Although precise mechanisms of its antianginal actions are still being delineated, CARDIZEM is believed to act in the following ways:

1. Angina Due to Coronary Artery Spasm. CARDIZEM has been shown to be a potent dilator of coronary arteries both epicardial and subendocardial. Spontaneous and ergonovine-induced coronary artery spasm are inhibited by CARDIZEM.
2. Exertional Angina. CARDIZEM has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand. This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal exercise work loads.

In animal models, diltiazem interferes with the slow inward (depolarizing) current in excitable tissue. It causes excitation-contraction uncoupling in various myocardial tissues without changes in the configuration of the action potential. Diltiazem produces relaxation of coronary vascular smooth muscle and dilation of both large and small coronary arteries at drug levels which cause little or no negative inotropic effect. The resultant increases in coronary blood flow (epicardial and subendocardial) occur in ischemic and nonischemic models and are accompanied by dose-dependent decreases in systemic blood pressure and decreases in peripheral resistance.

Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, diltiazem decreases sinoatrial and atrioventricular conduction in isolated tissues and has a negative inotropic effect in isolated preparations. In the intact animal, prolongation of the AH interval can be seen at higher doses.

In man, diltiazem prevents spontaneous and ergonovine-provoked coronary artery spasm. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load. Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative inotropic effect, cardiac output, ejection fraction, and left ventricular end diastolic pressure have not been affected. There are as yet few data on the interaction of diltiazem and beta-blockers. Resting heart rate is usually unchanged or slightly reduced by diltiazem.

Intravenous diltiazem in doses of 20 mg prolongs AH conduction time and AV node functional and effective refractory periods approximately 20%. In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block. Diltiazem-associated prolongation of the AH interval is not more pronounced in patients with first-degree heart block. In patients with sick sinus syndrome, diltiazem significantly prolongs sinus cycle length (up to 50% in some cases).

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PR interval, but has not usually produced abnormal prolongation. There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients.

Pharmacokinetics and Metabolism. Diltiazem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive first-pass effect, giving an absolute bioavailability (compared to intravenous dosing) of about 40%. CARDIZEM undergoes extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the urine. In vitro binding studies show CARDIZEM is 70% to 80% bound to plasma proteins. Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, hydrochlorothiazide, phenylbutazone, propranolol, salicylic acid, or warfarin. Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours. Desacetyl diltiazem is also present in the plasma at levels of 10% to 20% of the parent drug and is 25% to 50% as potent a coronary vasodilator as diltiazem. Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 ng/ml. There is a departure from dose-linearity when single doses above 60 mg are given, a 120-mg dose gave blood levels three times that of the 60-mg dose. There is no information about the effect of renal or hepatic impairment on excretion or metabolism of diltiazem.

INDICATIONS AND USAGE

1. **Angina Pectoris Due to Coronary Artery Spasm.** CARDIZEM is indicated in the treatment of angina pectoris due to coronary artery spasm. CARDIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occurring during attacks).
2. **Chronic Stable Angina (Classic Effort-Associated Angina).** CARDIZEM is indicated in the management of chronic stable angina. CARDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise tolerance.

There are no controlled studies of the effectiveness of the concomitant use of diltiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities.

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

1. **Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
2. **Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
3. **Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
4. **Acute Hepatic Injury.** In rare instances, patients receiving CARDIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes. (See PRECAUTIONS and ADVERSE REACTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS).

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women, therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this situation.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences, as well as their frequency of presentation, are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%), AV block (1.1%). In addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence.

Cardiovascular:	Flushing, arrhythmia, hypotension, bradycardia, palpitations, congestive heart failure, syncope.
Nervous System:	Paresthesia, nervousness, somnolence, tremor, insomnia, hallucinations, and amnesia.
Gastrointestinal:	Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH.
Dermatologic:	Pruritus, petechiae, urticaria, photosensitivity.
Other:	Polyuria, nocturia.

The following additional experiences have been noted:

A patient with Prinzmetal's angina experiencing episodes of vasospastic angina developed periods of transient asymptomatic asystole approximately five hours after receiving a single 60-mg dose of CARDIZEM.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: erythema multiforme; leukopenia; and extreme elevations of alkaline phosphatase, SGOT, SGPT, LDH, and CPK. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diltiazem has been limited. Single oral doses of 300 mg of CARDIZEM have been well tolerated by healthy volunteers. In the event of overdosage or exaggerated response, appropriate supportive measures should be employed in addition to gastric lavage. The following measures may be considered.

Bradycardia	Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.
High-Degree AV Block	Treat as for bradycardia above. Fixed high-degree AV block should be treated with cardiac pacing.
Cardiac Failure	Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics.
Hypotension	Vasopressors (eg, dopamine or levarterenol bitartrate).

Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating physician.

The oral/LD$_{50}$'s in mice and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively. The intravenous LD$_{50}$'s in these species were 60 and 38 mg/kg, respectively. The oral LD$_{50}$ in dogs is considered to be in excess of 50 mg/kg, while lethality was seen in monkeys at 360 mg/kg. The toxic dose in man is not known, but blood levels in excess of 800 ng/ml have not been associated with toxicity.

DOSAGE AND ADMINISTRATION

Exertional Angina Pectoris Due to Atherosclerotic Coronary Artery Disease or Angina Pectoris at Rest Due to Coronary Artery Spasm. Dosage must be adjusted to each patient's needs. Starting with 30 mg four times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four times daily) at one- to two-day intervals until optimum response is obtained. Although individual patients may respond to any dosage level, the average optimum dosage range appears to be 180 to 240 mg/day. There are no available data concerning dosage requirements in patients with impaired renal or hepatic function. If the drug must be used in such patients, titration should be carried out with particular caution.

Concomitant Use With Other Antianginal Agents:

1. **Sublingual NTG** may be taken as required to abort acute anginal attacks during CARDIZEM therapy.
2. **Prophylactic Nitrate Therapy**—CARDIZEM may be safely coadministered with short- and long-acting nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.
3. **Beta-blockers.** (See WARNINGS and PRECAUTIONS.)

HOW SUPPLIED

Cardizem 30-mg tablets are supplied in bottles of 100 (NDC 0088-1771-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1771-49). Each green tablet is engraved with MARION on one side and 1771 engraved on the other. CARDIZEM 60-mg scored tablets are supplied in bottles of 100 (NDC 0088-1772-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1772-49). Each yellow tablet is engraved with MARION on one side and 1772 on the other.

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Termination Without Extreme Prejudice — Amanita Phalloides

Ronald B. Mack, M.D.

I must admit she was beautiful; when she first came into view I was immediately struck by her lovely figure. Her stems were almost perfect. She was dressed perfectly for the warm weather, and a faint fragrance seemed to surround her. I impulsively wanted to grab this vision of loveliness and take her to dinner but I just could not; she was not alone nor was I. Besides, although she looked like an angel there is no question that she was wild, and people have since remarked that she has the reputation of being a killer. I was able to get her name — Amanita Phalloides (melodious, is it not? Probably foreign) but not her phone number or astrological sign. She was so gorgeous that you wanted to take a bite out of her.

Alright, I was only fooling — Amanita Phalloides is certainly extremely seductive and dangerous, but not as a person, for you see it is merely the name of one of the most toxic wild mushrooms in the world. It seems that there has been an increase in serious cases of mushroom poisonings in the U.S. in the recent past. There is probably no one reason for this increase but it is well known that many people love to search for and eat wild mushrooms. What is a mushroom after all? Mushrooms belong to a very large group of simple plants known as fungi; they possess no seeds, roots, flowers, chlorophyll or leaves. The mushroom is merely the fruiting part of the plant that is visible above ground — apparently most of the plant (a network of tiny threads) is hidden. (Think of this the next time you eat some.) There are probably 5000 species of mushrooms growing wild in the United States and 50-100 species are toxic. The Amanita Phalloides is only one of many toxic mushrooms but it is extremely poisonous and is thought to be responsible for the majority of fatal mushroom poisonings in Europe. It has only been positively identified as growing wild in our country since the 1970s.

Many people refer to these poisonous mushrooms as toadstools (don't let the name fool you, it does not mean frog doo-doo) which is derived from the Teutonic word for death. There are many very good references explaining the division of toxic mushrooms into groups but this paper will attempt to discuss the most toxic division, i.e., the *cyclopeptides* of which Amanita Phalloides is a prominent member. The toxins in this cyclopeptide group are unusually virulent and are believed to cause 95% of fatalities secondary to mushroom poisonings. The scariest genus in the cyclopeptide group is the Amanitas as has been mentioned, but why? These mushrooms contain thermostable toxins which are known as *amatoxins*. The amatoxins, especially one known as *amanitin*, destroy cells by inhibition of nuclear RNA polymerase II (now that sounds serious!!) and therefore interfere with both RNA and DNA transcription. The cells die and do not reproduce, especially those that are hit by the initial contact with the toxin and those with the most rapid rates of turnover, e.g. hepatocytes, renal tubular cells and GI tract mucosa cells.

To be perfectly frank, I find clinical toxicology very exciting (but then again I think Indira Gandhi is a real fox!!). To continue to be perfectly frank, inquiries from house staff or medical colleagues concerning mushroom ingestions can cause me to almost become anaphylactoid. They are not terribly easy cases for most of us to manage, let alone to pontificate upon. One of the better ways to approach this problem is to function according to the following general principle: the time of onset of symptoms following ingestion of a poisonous mushroom parallels rather closely the severity of the toxic encounter. There are exceptions of course, but the less severe, more-or-less self-limiting mushroom toxins cause abnormal clinical features within 15 to 120 minutes following ingestion. The really potent mushroom toxins, the ones that can kill, do not cause symptoms until 6 to 18 hours post ingestion. According to a recent book: "Exceptions always outnumber rules and there are always exceptions to established exceptions and by the time one masters the exceptions, no one recalls the rule."[1]

The Amanita mushrooms causing toxicity are of the long incubation type and this causes great consternation for the health care professional (the patient does not fare too well either) because it gives a false sense of security. To put it another way, mushrooms causing symptoms that are delayed for 6 to 24 hours after eating them are the ones that can kill the patient and it behooves you to try to diagnose these cases and stave off death if you can. The mortality rate is quite high indeed. The long latent period seen with Amanita ingestions may be due to the period of time necessary for the absorption of the toxin into the cells of the GI tract and the inhibition of RNA transcription to take place.

The clinical features of amanitin poisoning rather typically appear about 12 ± 2 hr after eating the poisonous fungus and classically is divided into three stages. In *Stage I* there are very severe abdominal cramps, nausea, vomiting and remarkably profuse watery diarrhea (which is best described as "Cholera-like"). This severe gastrointestinal

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From the Department of Pediatrics, Bowman Gray School of Medicine, Winston-Salem 27103.

insult can easily last 24-36 hours. Needless to say, the fluid and electrolyte loss can be formidable, leading at times to circulatory collapse. *Stage II* (AKA the latent stage) is present during the next 24 to 36 hours. In this phase there is often a remission in symptoms, especially if fluid and electrolyte replacement has been adequate; the patient appears to be recovering. It is in this stage, however, that laboratory values often look worse than the patient as liver enzymes rise, presaging severe hepatocellular damage and rising BUN and creatinine values allow you to note that renal damage is ensuing. *Stage III* (AKA the final stage and for many it unfortunately is) is the time where many of us feel like calling the patient's religious advisor. In this stage there is massive hepatic necrosis and icterus and acute renal failure as well as encephalopathy, coma, seizures, hypoglycemia, Stage VI bad breath, falling arches, hemorrhoids, etc. and as a health care provider you think you are witnessing the "One Horse Shay" phenomenon. (Remember this poem by Oliver Wendell Holmes where the author describes the breakdown of a carriage that seemed to fall apart all in one day.) Death is due to hepatic and renal failure and to secondary effects on the CNS and the cardiovascular system and usually occurs 4-7 days after eating the mushroom.

How do you go about diagnosing and treating such an awesome enemy as this? Certainly you should at least consider toxic mushroom ingestion in any case of more than simple acute gastroenteritis. Mushroom poisoning is more prevalent in the spring and fall as the moderate temperatures and wet conditions foster fungus growth. Do not forget that the later stages of amanitin poisoning resemble Reye's Syndrome or severe acetaminophen poisoning. If the truth were known there are several conditions that can simulate this poisoning clinically, e.g., poisoning due to carbon tetrachloride or ferrous sulfate or phenylbutazone to name a few. In a perfect world you would make every effort to identify the mushroom you believe is making your patient sick. But this is an imperfect world and not many of us are mushroom experts. You are very fortunate if your area has an experienced mycologist available; ask the college or high school botany teachers if they can help you or the local plant store manager who is often a good source for plant ingestions in general.

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The treatment of amatoxin poisoning is mainly supportive with careful attention being paid to the restoration of fluids and clotting factors and the minimizing (if possible) of the renal and/or hepatic failure. Many other treatments have been tried but most are anecdotal and there are no good controlled studies to prove or disprove their efficacy. This is a difficult poison to obtain good data about; how do you measure how much toxin the patient ingested? Apparently most of the amatoxin is excreted within six hours of ingestion whereas many patients seek treatment later than six hours. The treatments that have been suggested include repeated doses of activated charcoal, the use of steroids, cytochrome c, penicillin, thioctic acid and extracorporeal removal of the toxin. Others such as emulsed rabbit brains or horse serum antitoxins are not even considered reasonable choices these days but were at one time. The only therapy that experts seem to agree on is careful monitoring of the patient and replacement therapy as indicated.

I would be remiss if I left the subject of Amanita Phalloides intoxication without mentioning the use of the controversial "antagonist" *thioctic acid*. This product, AKA alpha lipoic acid, is a Krebs cycle coenzyme which is thought to ameliorate hepatocellular damage. Thioctic acid has advocates who believe it is extremely helpful in preventing death in Amanita Phalloides poison cases (as well as other Amanita species), and it has detractors who do not believe it works at all. It is considered a reasonably safe product and the only side effect so far seems to be hypoglycemia. *It cannot be emphasized too strongly that there are no controlled studies regarding the use of this drug.* Thioctic acid allegedly is efficacious even after hepatic and/or renal necrosis has begun. My sense of the current literature regarding this toxin and this antidote does not suggest that you do not use it. Some of my most respected reference source people do consider using it and I would not hesitate to use it either if I felt it was indicated. The catch is that thioctic acid is currently available only from Dr. Burton Berkson of Hobbs, New Mexico — 505/392-6581.

When I think of mushrooms I think of what one of our housestaff said to me recently. He complained that he felt at times like a mushroom because he was kept in the dark and fed road apples. Bon Appetit!!

Reference

1. Block A. *Murphys Law — Book Three*. Los Angeles: Price, Stern, Sloan, Inc., 1982.

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Precautions: *CNS Effect.* Use cautiously in patients prone to seizures; seizures have occurred though no cause and effect relationship has been established. Therapeutic doses have in rare instances, resulted in hallucinations (usually visual), disorientation, and confusion, which cleared spontaneously within a period of hours. Such patients should be very closely observed and vital signs checked; if the drug is reinstituted, it should be done with caution since the acute CNS manifestations may recur. *Impaired Renal or Hepatic Function.* Decreased metabolism of pentazocine in extensive liver disease may predispose to accentuation of side effects; it should be administered with caution in renal or hepatic impairment. In long-term use, precautions should be taken to avoid increases in dose by the patient. *Biliary Surgery.* Some evidence suggests that unlike other narcotics pentazocine causes little or no elevation in biliary tract pressures; the clinical significance of these findings is not yet known. *Information for Patients.* Since sedation, dizziness, and occasional euphoria have been noted, ambulatory patients should be warned not to operate machinery, drive cars, or unnecessarily expose themselves to hazards. May cause physical and psychological dependence taken alone and may have additive CNS depressant properties in combination with alcohol or other CNS depressants. *Myocardial Infarction.* Use with caution in patients with myocardial infarction who have nausea or vomiting. *Drug Interactions. Usage with Alcohol.* See **Warnings**. *Carcinogenesis, Mutagenesis, Impairment of Fertility.* No long-term studies in animals to test for carcinogenesis have been performed. *Pregnancy Category C.* Should be given to pregnant women only if clearly needed. *Labor and Delivery.* Use with caution in women delivering premature infants. Effect on mother and fetus, duration of labor or delivery, need for forceps delivery or other intervention or resuscitation of newborn, or later growth, development, and functional maturation of the child is unknown. *Nursing Mothers.* Caution should be exercised when administered to a nursing woman. *Pediatric Use.* Safety and effectiveness in children below the age of 12 years have not been established.

Adverse Reactions: *Cardiovascular.* Hypotension, tachycardia, syncope. *Respiratory.* Rarely, respiratory depression. *CNS. Acute CNS Manifestations.* In rare instances, hallucinations (usually visual), disorientation, and confusion which have cleared spontaneously within a period of hours, may recur if drug is reinstituted. *Other CNS Effects.* Dizziness, lightheadedness, sedation, euphoria, disturbed dreams, hallucinations, irritability, excitement, tinnitus, tremor. *Gastrointestinal.* Nausea, vomiting, constipation, diarrhea, anorexia, rarely abdominal distress. *Allergic.* Edema of the face, dermatitis, including pruritus, flushed skin, including plethora. *Ophthalmic.* Visual blurring and focusing difficulty. *Hematologic.* Depression of white blood cells (especially granulocytes), which is usually reversible, moderate transient eosinophilia. *Other.* Headache, chills, insomnia, weakness, urinary retention.

Drug Abuse and Dependence: *Controlled Substance.* TALWIN Nx is a Schedule IV controlled substance.

Dependence and withdrawal symptoms have been reported with orally administered pentazocine. Patients with a history of drug dependence should be under close supervision. Possible abstinence syndromes in newborns after prolonged use of pentazocine during pregnancy have been reported. In prescribing for chronic use, the physician should take precautions to avoid increases in dose by the patient. Tolerance to the analgesic effect is rarely reported; there is no long-term experience with oral use of TALWIN Nx.

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Selenium Intoxication — New York

ON December 27, 1983, a 57-year-old female in New York began taking a daily selenium supplement distributed by Brite Years, Inc., of Tempe, Arizona. The label on the 90-tablet bottle recommended taking one of the 150-mcg tablets daily. She took the prescribed number in addition to her usual daily vitamins, which included: vitamin C (1000 mg, plus bioflavinoids, thrice daily); vitamin A (10,000 units once daily); vitamin D (400 units once daily); vitamin E (400 units once daily); B complex (once daily); and a high-potency mineral supplement labeled as containing all 72 trace elements in undefined quantities, as well as calcium, magnesium, phosphate, potassium, zinc, iron, manganese, and iodine. She consumed at least one vitamin C tablet (1000 mg) simultaneously with the selenium supplement.

Approximately 11 days after starting the selenium supplement, the patient noted marked hair loss limited to her scalp, which progressed over a 2-month period to almost total alopecia. Two weeks later, she noted white horizontal streaking on the fingernail of her left fifth digit, tenderness and swelling on the fingertip, and purulent discharge from the fingernail bed. This progressed over a 3-week period to involve all fingernails. The patient subsequently lost the entire fingernail of her left fifth digit. In addition, she experienced periodic episodes of nausea and vomiting, a sour-milk breath odor, and increasing fatigue. In January, she consulted a dermatologist for her hair loss and nail changes and was treated with oral erythromycin for paronychia. Her alopecia was attributed to emotional stress following the death of her husband a year earlier.

On March 11, 1984 she heard on the radio that the selenium tablets distributed by Brite Years, Inc., were being recalled because of superpotency. She stopped taking the tablets and consulted her internist. She had consumed 77 of the 90 tablets. A serum selenium level from March 15 was reported as 528 ng/ml, approximately four times the normal levels for the U.S. population.[1]

The distributor voluntarily recalled the product when analysis of the selenium tablets from one lot revealed a selenium level of 27.3 mg per tablet (182 times higher than labeled). The implicated tablets were reportedly manufactured by Superior Health Vitamin and Health Foods in Deer Park, New York, for the distributor. These tablets were part of approximately 250 bottles distributed to 39 accounts in 15 states (Alaska, Alabama, Arizona, Arkansas, California, Iowa, Missouri, Montana, New York, Ohio, Oregon, Pennsylvania, Texas, Utah, and Virginia) from four distribution lots (codes 012163, 016213, 301216, and 12161). Subsequent analyses of tablets from all four implicated distribution lots have contained 25 mg of sodium selenite and 4 mg-5 mg total of elemental and/or organic selenium. Analysis of tablets taken from the symptomatic woman in New York found 31 mg of total selenium per tablet.

Reported by R Jensen, DO, W Closson, PhD, Brunswick Hospital, Amityville, R Rothenberg, MD, State Epidemiologist, New York State Dept of Health; Emergency and Epidemiological Operations Br, Brooklyn District Office, U.S. Food and Drug Administration; Cancer Prevention Studies Br, Div of Cancer Prevention and Control, National Cancer Institute; Office of the Director, Epidemiology Program Office, CDC.

Editorial Note: Selenium is widely, though irregularly, distributed in soil, forages, and grains and has many commercial uses. Human intake of selenium comes mainly from cereal, fish, and meat in the diet and, in residents of one city studied, averaged 81 mcg per day.[2] While there is no established recommended daily allowance, the proposed adequate and safe intake of selenium in adults is 50 mcg-200 mcg daily.[3] Until lately, there were no well-documented cases of human selenium toxicity. A recent study reported a number of villages in the People's Republic of China where high percentages of individuals had nail and hair loss, dermatitis, nausea, garlic odor on their breath, fatigue, irritability, and hyperreflexia.[4] Individual daily dietary selenium intake in this area ranged from 3.20 mg to 6.69 mg (averaged 4.99 mg), and whole blood levels of selenium ranged from 1300 ng/ml to 7500 ng/ml (average 3200 ng/ml).*

The signs and symptoms exhibited by the New York woman were almost certainly due to selenium intoxication. The estimated cumulative dose of selenium she ingested over the 77 days was 2.387 mg. Her toxicity was probably minimized by the simultaneous ingestion of large doses of vitamin C. Vitamin C reduces selenite to elemental selenium that is poorly absorbed.

This incident demonstrates that excessive doses of trace elements can have toxic effects. Implementation of improved quality-control measures in the manufacture of these food supplements could help alleviate problems of this nature in the future. With the general increase in use of vitamin and mineral supplements in this country, the public and the medical community should be aware of the potential for toxicity.

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* Whole blood selenium measurements are approximately 30% higher than serum selenium.

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For further information about Charter Northridge contact:

Hospital Administrator: Tony Mobley

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NEWS FROM CDC

Infant Botulism — Massachusetts

A previously healthy 5-month-old male infant was admitted to a Massachusetts hospital in November 1983 with progressive lethargy and loss of developmental milestones over 3 weeks, constipation for 12 days, and poor suck and feeding. He had been breast-fed, and bottled foods were added at the age of 3 months. On examination, the child was generally hypotonic with flaccid extremities, no head control, and no suck or Moro reflexes. He was alert, able to smile, and had no oculomotor weakness. An electromyogram revealed a post-tetanic facilitation pattern after stimulation at 50 Hz, compatible with infant botulism. He was initially treated with intravenous hydration and saline enemas. Naso-gastric feedings were begun on the fourth hospital day, and he improved gradually thereafter. Type B botulinal toxin and *Clostridium botulinum* were identified in a stool specimen by the Massachusetts State Laboratory.

Reported by DG Sidebottom, MD, Children's Hospital, Boston, JP Reardon, MD, MB Holmes, NJ Fiumara, MD, State Epidemiologist, Massachusetts Dept of Public Health; Enteric Diseases Br, Div of Bacterial Diseases, Center for Infectious Diseases, CDC.

Editorial Note: Infant botulism, in contrast to foodborne botulism resulting from ingestion of preformed toxin, is caused by *C. botulinum* toxin produced in and absorbed from the gastrointestinal tract, leading to neurologic manifestations. This report represents the first case of infant botulism identified in Massachusetts and the second from the New England states; the first reported case occurred in 1983 in Connecticut. Infant botulism was first identified in 1976; four states — California, Texas, Pennsylvania, and Tennessee — reported cases that year. To date, 36 states in all geographic regions, including Alaska and Hawaii, have identified cases. Between 1976 and 1983, 395 cases were reported to CDC. Patients' ages ranged from 2 to 38 weeks, and 204 (53%) were male; most were hospitalized, and 11 died. Type A botulinal toxin was identified in 50% of the cases; type B, in 49%; and types F and B/F, in one case each.

A case-control study performed by the California Department of Health Services in 1976-1978 showed that infants with type B botulism were more likely than controls to have been fed honey, and type B spores were identified in implicated honey samples.[1] This is the only exposure that is a clearly defined risk factor for cases of infant botulism, and CDC has recommended that honey not be fed to infants under 1 year of age.[2] In a 1976-1980 epidemiologic study of infant botulism cases reported through CDC's surveillance system from states other than California, 96 infant botulism patients were compared with infants in the general population; infant botulism patients tended to have higher birth weights, and their mothers tended to be older and better educated.[3] Seventy percent of the botulism patients were predominantly breast-fed.

For patients in whom the diagnosis of infant botulism is considered, physicians should collect stool specimens for toxin testing and culture and should contact their state health departments for processing specimens. Treatment is mainly supportive, with gradual recovery in most cases. Enemas may be given to help eliminate toxin from the gastrointestinal tract. The roles of botulinal antitoxin and antimicrobials in treatment are unclear.

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ALLIED HEALTH PROFESSIONS

Characteristics of Emergency Medical Services Providers in Rural Areas Who Seek Advanced Training

Theodore W. Whitley, Ph.D., Sandra S. Landis, R.N., and E. Jackson Allison, Jr., M.D./M.P.H.

THE growth and development of emergency medical services in the United States during the last two decades have been documented.[1, 2] Major advances in the development of training courses and textbooks have been made, and a system for registering emergency medical technicians (EMTs) has been established.[3] As a result of the initiative of the federal government,[4] emergency medical services are being provided by larger numbers of well-trained individuals operating from well-equipped vehicles. However, little has been reported about the personal characteristics of these individuals or their motivation for becoming emergency care providers. Therefore, the purpose of this article is to describe a group of people who have been trained to provide pre-hospital emergency care in eastern North Carolina and some aspects of their training process.

The passage of the Emergency Medical Services Systems Act of 1973 was a major cause of the rapid expansion of emergency medical services during the past decade. This legislation, which provided funds for planning emergency medical services, implementation of basic life support services, and implementation of advanced life-support services,[2] permitted emergency medical systems to become more sophisticated. In addition, the 81-hour training course for EMTs available from the National Highway Traffic Safety Administration (NHTSA) of the United States Department of Transportation has become more widely accepted, and the National Registry of Emergency Medical Technicians has developed a system for classifying EMTs on the basis of their training and competence.[1]

The three classifications used by the National Registry, which correspond to the classifications identifying training programs developed by NHTSA, are EMT, EMT-Ambulance (EMT-A), and EMT-Paramedic (EMT-P).[1] Individuals in the first two classifications have completed the NHTSA program, but individuals certified at the EMT-A level have passed a certifying examination administered by the National Registry. Individuals certified at the EMT-P level by the National Registry have satisfactorily completed a course covering advanced emergency care procedures and passed a certifying examination. Due to the advanced training provided in programs beyond the EMT-A level, these programs frequently are referred to as advanced life support (ALS) training programs.

North Carolina does not use the National Registry classification system. In fact, certification by the National Registry is not required in North Carolina. While some states do use the National Registry examination for certification at the state level, other states, including North Carolina, require individuals to successfully complete an examination developed and administered by a state agency. EMTs certified in North Carolina may seek National Registry certification if they wish.

A comparison of the classification systems used by the National Registry and by North Carolina is presented in table 1, as well as a brief description of the training requirements for certification at each level in North Carolina. Individuals who complete the basic level of training in North Carolina are called Emergency Medical Technicians (EMT), but their training corresponds to that of an EMT-A in the National Registry system. Also, the training required at the EMT-P level in North Carolina corresponds to that required by the National Registry. However, North Carolina has created a third certification level, Emergency Medical Technician-Intermediate, or EMT-I.[5] Examination of table 1 reveals that individuals certified at this level have completed a training program of at least 30 hours beyond that required for EMT certification and are qualified to initiate intravenous fluid therapy, to perform esophageal obturator airway intubation, and to withdraw blood for laboratory tests.

Despite the rapid development of emergency medical services at the national level, the majority of emergency care in rural eastern North Carolina is still provided by volunteer rescue squads or volunteer emergency medical services.[6] These groups, although committed to providing quality care, have little time for completing grant applications and little experience in seeking funds from external sources such as government agencies or private foundations. Consequently, funds for developing and implementing training programs have been scarce. In addition, the small number of communities supporting large medical centers has contributed to the difficulty encountered in providing training at all three levels and has made desired levels of medical direction difficult to attain.

During the past five years, many medical and nonmedical groups have worked together to obtain the finan-

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From the Department of Emergency Medicine, East Carolina University School of Medicine, Greenville 27834.

TABLE 1
The relationship between the training programs for emergency medical technicians prescribed by the National Registry of Emergency Medical Technicians and the North Carolina Board of Medical Examiners*

National Registry	North Carolina	North Carolina Requirements			EMS Project Requirements		
		Course Hours	Course Content	Examinations	Course Hours	Course Content	Examinations
EMT-A†	EMT	71 didactic 10 clinical 81 total	EMS System Extrication Determining the Extent of Injury Transfer Techniques	Written: 160 items Practical Skills: 1. assessment 2. splinting 3. CPR 4. vital signs 5. airway 6. spinal immobilization (6 stations total)	No course offered		
	EMT-I	27 total	Terminology & Professionalism Cardiovascular System Shock & Fluid Therapy Respiratory System-EOA Portion 6 successful IV starts in classroom 10 successful IV starts in clinical	Written: 160 items Practical Skills:‡ (6 EMT skills repeated) Additional Practical Skills: 1. IV insertion 2. venipuncture for blood withdrawal 3. EOA insertion (9 stations total)	111 didactic 30 clinical 141 total	Terminology & Professionalism Shock & Fluid Therapy Skills: 1. IV 2. EOA 3. MAST Systems Review Assessment of Pathologic States	Pretest: 60 items Posttest: 60 items Practical Skills: 1. IV & fluid therapy 2. venipuncture for fluid therapy 3. MAST 4. case study
EMT-P	EMT-P	200 lecture, practical and evaluation 218 clinical 418 total	General Pharmacology Respiratory System Central Nervous System Soft Tissue Injuries Musculoskeletal System Medical Emergencies Obstetric/Gynecology Emergencies Management of the Emotionally Disturbed Rescue Techniques Telemetry & Communications	Written: 160 items Practical Skills: (6 EMT & 3 EMT-I skills repeated) Additional Practical Skills: 1. endotracheal intubation 2. medication administration 3. defibrillation (12 stations total)	180 didactic 4 self-study weeks (at 15 hrs/wk) 150 clinical and field 390 total	Terminology & Professionalism Skills: 1. Airway Mgt. 2. EKG recording Dysrhythmia Interpretation Pharmacology Assessment & Field Intervention Management of Cardiac Dysrhythmias Rescue Techniques Communication of Vital Information Review	Pretest: 60 items Posttest: 100 items Practical Skills: (4 EMT-I Skills repeated) Additional Practical Skills: 1. defibrillation 2. pharmacology 3. endotrachael intubation 4. case study (8 stations total)

* The North Carolina Office of Emergency Medical Services is the agency responsible for the administration of ALS training programs for Emergency Medical Technicians and serves as liaison between providers and the Board of Medical Examiners.
† Any certified EMT from any state may obtain this classification by passing an examination administered by the National Registry.
‡ Testing of practical skills at the EMT-I and EMT-P levels is the responsibility of the local medical director of the training program.

cial resources necessary to expand emergency medical services in eastern North Carolina. One result of these efforts was the procurement of a $500,000 grant from the United States Department of Health and Human Services,[7] which was awarded in 1980 for one year. Matching funds from local sources doubled the amount of money available to $1,000,000. These funds were used primarily to purchase communications equipment as well as equipment for emergency departments and ambulances.

Public awareness of emergency medical services generated by community efforts, physician involvement, and the availability of grant funds led to an increase in the number of EMTs who wished to obtain certification at the EMT-I level. The Emergency Medical Services (EMS) Project was established by the East Carolina University School of Medicine (ECUSOM) in 1979 to help provide this training. The project is administered by the Department of Emergency Medicine at ECUSOM and provides education, training, and community support in the 29-county region of eastern North Carolina.

Program

The ALS training programs developed by the EMS Project as outlined in table 1 are designed to provide quality training which meets both state and federal standards. The Department of Emergency Medicine at East Carolina University School of Medicine is very sensitive to the need to develop ALS programs that are responsive to community needs and permit people in the communities to manage them. As a result, the initial efforts of the project staff were directed not only toward the development of a curriculum, but also toward informing physicians, hospital administrators, nurses, and other support staff about the training of EMT-Is and the kinds of services they could provide. This informational process was, and still is, considered particularly important because hospitals and their medical staffs must be willing to accept responsibility and liability for the care provided by EMT-Is under their sponsorship. In addition, medical personnel from the sponsoring hospitals have served to augment the core faculty enlisted by the EMS Project to teach in the program and have played an active role in the training programs initiated by rescue squads in their communities.[6]

The curriculum used to train EMT-Is has been described in detail.[6] Briefly, the curriculum is based on a course guide available from the United States Department of Transportation.[8] Four modules from this guide have been adapted for use by project faculty: a) The Emergency Medical Technician, his role, responsibility, and training, b) Human systems and patient assessment, c) Shock and fluid therapy, and d) The respiratory system. The course consists of 141 hours divided into 75 hours of didactic instruction, 30 hours of precepted clinical experience, 27 hours of EMT recertification instruction, 3 hours of ALS skills examination, and 6 hours required to take the certification examination administered by the North Carolina Office of Emergency Medical Services.

In addition to the core faculty, standard curriculum, and precepted clinical experience, several other steps are taken to insure that EMT-Is trained by the EMS Project will be able to provide appropriate care. For example, a written pretest designed to assess knowledge and skills which should have been acquired during training for certification as an EMT and through experience as an EMT is administered to each prospective trainee. The potential candidate is then screened by members of the local medical community, members of the staff of the sponsoring hospital and members of the rescue squad requesting the training program. Each trainee who completes the program also takes a posttest and is interviewed by the same panel. The purpose of the second interview is to determine which trainees should be recommended to the North Carolina Board of Medical Examiners as candidates for the certification examination administered by the Office of Emergency Medical Services.

Characteristics of Providers

Individuals willing to undergo the training required to become certified at the EMT-I level and willing to assume the responsibility for providing pre-hospital care appropriate to this level of training are a special group. The remainder of this paper is devoted to describing some of the personal characteristics of individuals from eastern North Carolina who seek to acquire ALS skills and to explore some possible reasons for their willingness to assume the responsibility for providing emergency care.

In general, the trainees enrolled in the EMS Project during the past two years are young. Their ages range from 18 (the statutory limit) to 59 years with 83.1% under 40 and 3.4% 50 years old and older. The mean age is 31.3 years and the median age is 29.4 years. This age range is reflected in the amount of EMS experience of the trainees. While the range of experience extends from less than one year to 14 years, the mean is only 3.6 years and the median is 2.9 years. In fact, 2.4% of the trainees have less than one year of experience, 78.5% have one to five years, and 97.6% have less than 10 years.

The educational attainment of the trainees also reflects their relatively young age. Specifically, 53.4% have a high school degree or less education, and only 12.5% have completed 16 or more years of education. However, 29.4% of the trainees have attended a college or university for some period of time, and a surprisingly small percentage (13.9%) have attended a technical institute or community college. Only 2.3% of the trainees have not earned a high school diploma, and only 1.8% have obtained a high school diploma via the Tests of General Education Development. As would be expected from the percentage of trainees in each category, the mean educational achievement is 14.7 years; the median is 12.5 years.

The trainees are employed in a variety of occupations (table 2). The relatively high percentage of EMS professionals may be perplexing until two facts are considered. First, as might be expected, units employing EMS professionals have been quick to seek training through the EMS Project. Second, these units are interested in providing ALS training for new employees as quickly as possible. Therefore, several squads employing EMS professionals have requested two or three training programs. As more squads and services comprised of volunteers receive training, the percentage of EMS professionals will reflect the

TABLE 2

Distribution of EMS Providers Enrolled in the EMT-I Training Program by Occupation

Occupation	Frequency	Percent
Fire Fighter	15	6.8
Law Enforcement	10	4.5
Nurse	14	6.3
Teacher	4	1.8
Farmer	4	1.8
Industry/Commerce	34	15.4
Executive/Manager	7	3.2
EMS Professional	70	31.7
Other (unspecified)	4	1.8
Other Health Field	8	3.6
Military	7	3.2
Student	4	1.8
Housewife	12	5.4
Clerical	6	2.7
Government Employee	3	1.4
Clergy	1	0.5
Mechanical/Maintenance	4	1.8
Barber	1	0.5
Retired	1	0.5
Engineer	1	0.5
Journalist	1	0.5
Unknown	10	4.5
Total	221	100.0

actual composition of ALS providers in the region more accurately.

In a similar manner, the percentage of full-time EMTs (37.4%) in relation to volunteer EMTs (55.9%) and part-time EMTs (6.6%) is somewhat unrepresentative of the region. These data should change over time, however, for the reasons mentioned in the preceding paragraph. A dramatic increase in the number of full-time paid EMTs in the region seems unlikely in the immediate future.

The most appealing explanation for the willingness of the individuals described in the preceding paragraphs to obtain ALS training is the fact that they will be providing services in the communities in which they live. In many instances, they will be acquainted with the people receiving their services. Whatever their reasons, these individuals are willing to make a substantial time commitment to become EMT-Is.

This time commitment begins with the initiation of training. As noted previously, the training program consists of 141 hours. Classes are held at night to accommodate trainee work schedules. The potential drawback to this schedule is that trainees, particularly volunteers, frequently voice their expectation that all learning will occur during classes. This impression is probably compounded by the relative youth of the trainees and the fact that many have had no exposure to higher education. Consequently, the only assignments that require time outside of class involve reading the required textbook. Since 83% of the trainees known to have taken the state certification examination passed it, these potentially troublesome educational factors apparently can be overcome.

The time commitment does not end with certification. Members of rescue squads must respond to calls during work hours. Moreover, these calls may be to locations at some distance from the EMT's place of work. Except for EMS professionals, EMTs must complete the tasks at their workplace when they return. Finally, calls at night reduce the time available for leisure and/or family activities.

Conclusion

A group of young men and women with diverse educational and occupational backgrounds is willing to assume responsibility for providing emergency medical services in communities in rural eastern North Carolina. They are also willing to make a significant time commitment to secure the training required to provide these services. The results of the state certification examination indicates that participants in the EMS Project have acquired the skills taught at the EMT-I level and can apply what they have learned.

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IN STATE

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Malpractice Awareness — STAT
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Info: Wayne Parker. 919/828-9334

August 15

Electrolytes/Arterial Blood Gases/Fluid Balance
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Credit: 2 hours
Info: R. S. Cline, M.D., Central Carolina Hospital, 1135 Carthage St, Sanford 27330. 919/774-4100, ext 394

August 21

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August 24, 26

Summer Urology Conference
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Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103

September 9-12

Basic Clinical Teaching Skills
Place: Rougemont
Credit: 20 hours Category 1 and AAFP
Info: Katharine Munning, 407 Crutchfield Street, Durham 27705. 919/471-2571.

September 9-13

Clinical Skills Workshops and Review
Place: Winston-Salem
Credit: 31 hours Category I
Fee: $395
Info: Elizabeth B. Philp, Department of Family Medicine, Bowman Gray School of Medicine, Winston-Salem 27103.

September 11

New Developments in Clinical Medicine
Place: Fayetteville
Credit: 7 hours AAFP
Info: Mary Henley. 919/323-1152.

September 21

Sixth Annual Health Law Forum
Place: Greenville
Info: Mary Valand, Box 7224, ECU School of Medicine, Greenville 27834. 919/758-5200.

September 21-22

New Advances in the Treatment of Sickle Cell Disease
Place: Wrightsville Beach
Credit: 8 hours Category I
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September 28-29

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October 1-5

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October 1-5

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October 3

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October 13-14

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October 24-27

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October 26-27

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Place: Chapel Hill
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October 26-27

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November 1-2

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November 11-14

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Info: Jean E. Shelton, M.D., Children's Hospital of the King's Daughters, 800 West Olney Road, Norfolk, VA 23507. 804/628-3798

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November 13
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For further information please contact either Dr. Sessions or Dr. Bozymski at 919/966-2511 or Alice Rupen, Crohn's Study Coordinator, at 919/966-5800.

- Drs. Eugene Bozymski and Roy Orlando are conducting two clinical studies at the University of North Carolina at Chapel Hill. One study concerns the efficacy and safety of Sucralfate suspension in the treatment of symptomatic reflux esophagitis. Patients with symptoms of heartburn and endoscopic/histologic evidence of esophagitis are eligible for this study. We are also studying the efficacy of oral prostaglandins on benign gastric ulcer healing. These two studies are being conducted without cost to the patient. If you have any patients who might be suitable and interested, please contact Dr. Eugene Bozymski, Dr. Roy Orlando, or Debbie Buddin, MSN at the UNC School of Medicine 919/966-2511. At the completion of the study patients will be returned to the care of their personal physician.

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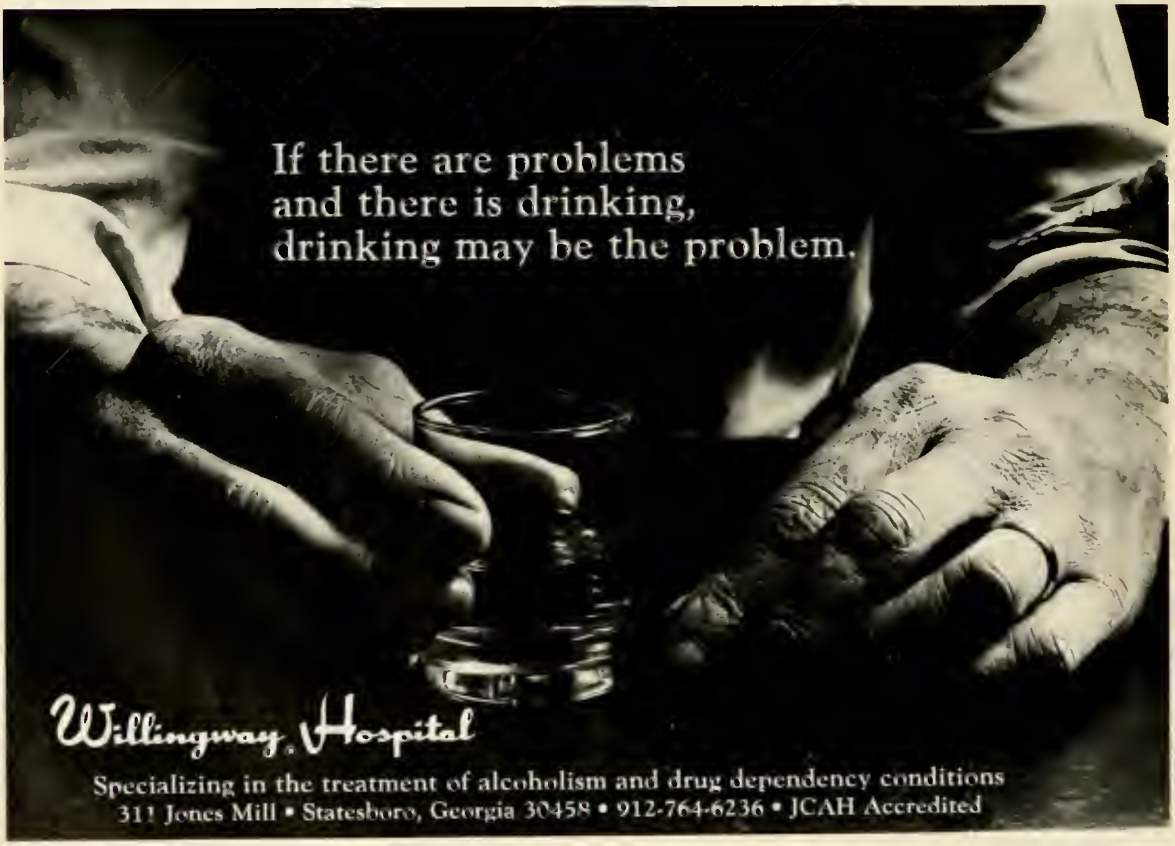
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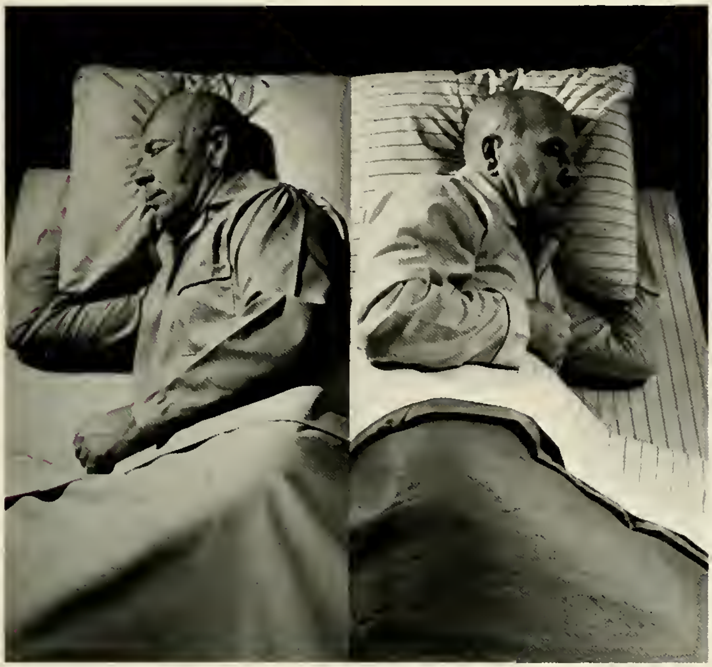

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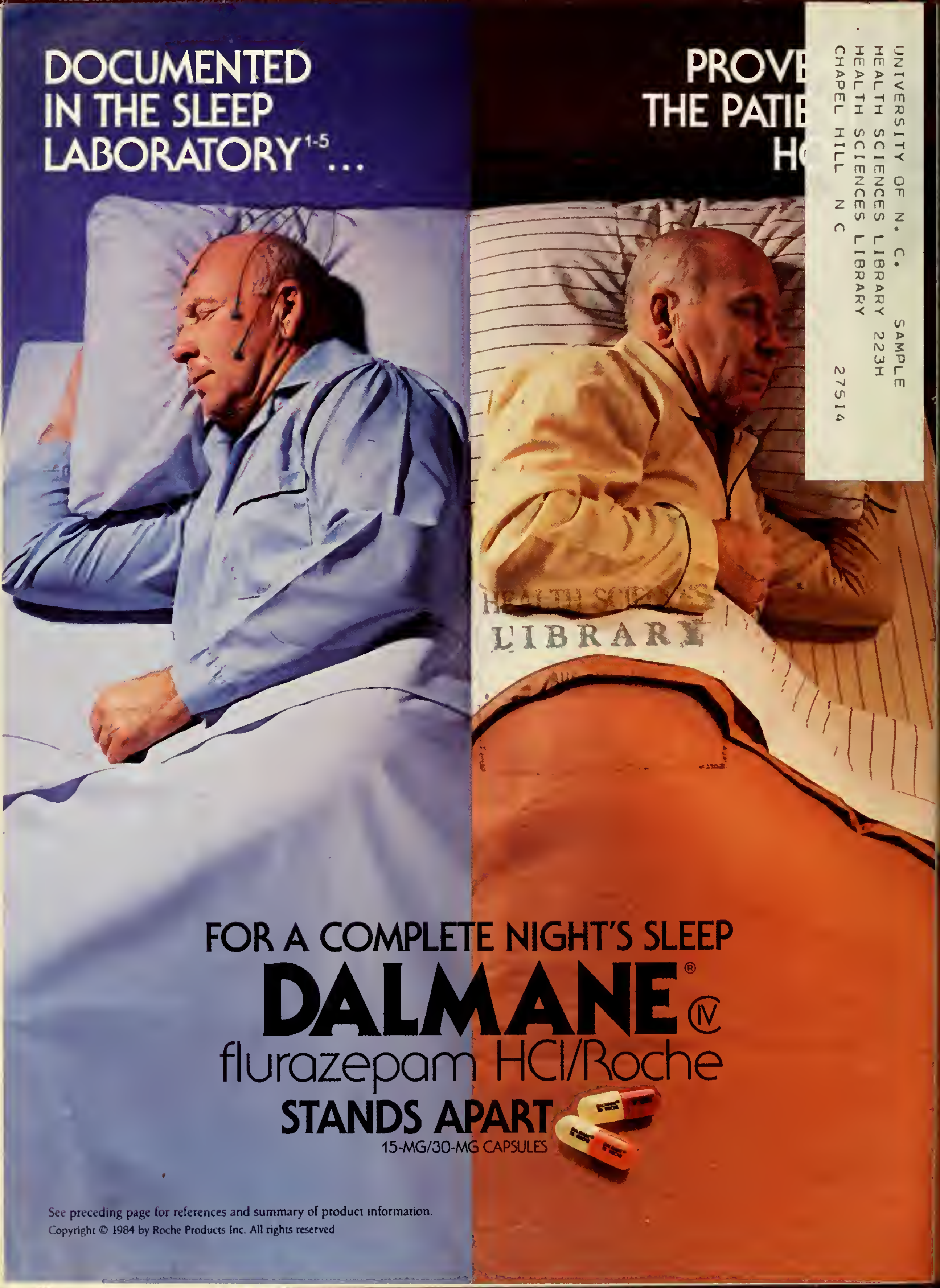

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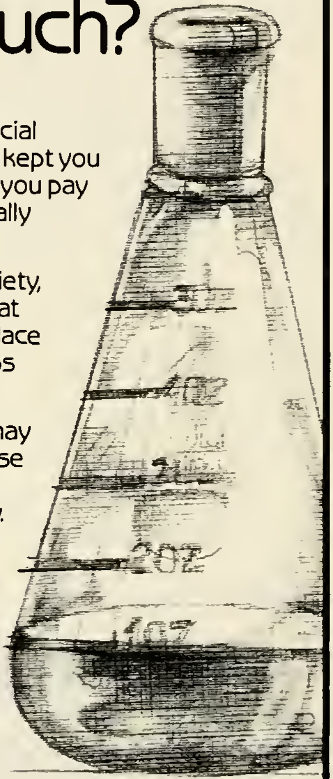

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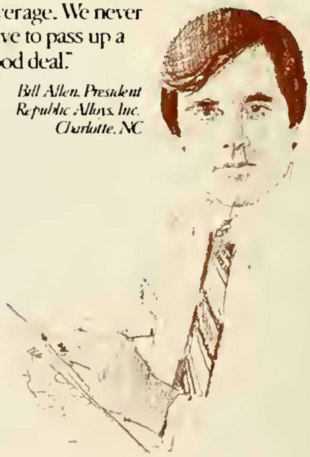

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SCIENTIFIC ARTICLE

Update — The Sudden Infant Death Syndrome in North Carolina

Marianna M. Henry, M.D., Evangeline S. Getzen, M.P.A., Kay A. McNeill-Harkins, R.N., M.P.H., and Gerald L. Strope, M.D.

• *An update on the occurrence of SIDS in approximately 150 North Carolina infants each year.*

EACH year in North Carolina 140-160 infants die of sudden infant death syndrome (SIDS). Many additional infants present with apnea and are thought to be at increased risk for sudden, unexplained death. Professionals from several disciplines are currently working with families of SIDS victims and high risk infants in this state. The purpose of this report is to review briefly the epidemiology and etiology of SIDS, the management of SIDS deaths, the evaluation of infants with apnea, and the options available to physicians and parents of infants thought to be at increased risk of SIDS in North Carolina.

Epidemiology

The sudden infant death syndrome is defined as the sudden death of any infant which is unexpected by history and unexplained after a postmortem examination. Approximately 7,000 deaths each year in the U.S. are attributable to SIDS, making this syndrome the greatest single cause of death in the age group from one month to one year. SIDS accounts for nearly one third of all postneonatal infant deaths.

Several characteristics of SIDS emerge from available epidemiologic data. The peak incidence occurs at age two to four months with relative sparing of the infant less than one month old. Ninety percent of SIDS deaths occur during the first six months of life. A seasonal pattern is suggested by an increased incidence during the winter months. Affected infants are generally perceived as well; however, many have had recent mild upper respiratory infection. Death tends to occur at night while the infant sleeps but may occur during the day under a variety of other circumstances.

The incidence of SIDS in North Carolina during 1979-82 was 1.78/1000 live births, approximately the same as the national incidence. The sex and race related incidences of SIDS for 1979-82 are shown in table 1. Males were affected more commonly than females (male:female 1.43:1). The incidences in the black and Indian populations were greater than in the white population (2.70, 2.88, and 1.33/1000 live births, respectively). These race related incidences are similar to those reported by Blok[1] except that the incidence in the Indian population during 1979-82 was considerably lower than he reported in North Carolina during 1972-74 (2.88 vs 6.56/1000 live births). The small number of Indian births each year and inaccurate racial designation based on incomplete family information may contribute to these differences in SIDS rates. The effect of socioeconomic background on these differences in race related incidence is unknown. The incidence of SIDS by county during 1979-82 is shown in figure 1. County incidences ranged from 0-6.6/1000 live births. (North Carolina SIDS data are provided by the North Carolina SIDS Project Office. Data are based on autopsy information available in 95% of cases primarily from the office of R. Page Hudson, M.D., Chief Medical Examiner of North Carolina.)

Risk Factors for SIDS

Numerous maternal and infant risk factors for SIDS have been identified. Maternal risk factors include: maternal age of less than twenty years, single marital status, delayed initiation of prenatal care or few prenatal visits for medical care, chronic disease during pregnancy, low socioeconomic status, smoking, and heroin addiction. Known infant risk factors relate primarily to prematurity and family history of SIDS. Specific risk factors include: prematurity (7/1000 live births), multiple births (3.8/1000 for twins and 8.3/1000 for triplets), sibling of SIDS (20/1000), and repetition of SIDS in multiple births (42/1000). The risk to cousins of SIDS victims is thought to be about the same as the risk for the general population (2.2/1000).[2]

Pathogenesis

Though the etiology of SIDS remains obscure, our understanding of this disorder has broadened in recent years. Many SIDS victims are no longer considered to be normal prior to death. Approximately two-thirds of SIDS victims examined in special pathologic studies have been found to have evidence of chronic tissue hypoxia as demonstrated by hypertrophy and hyperplasia of pulmonary arterial musculature with the abnormal extension of musculature into more peripheral pulmonary arterioles, right ventricular hypertrophy, extramedullary hematopoiesis, and

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From the Department of Pediatrics, The University of North Carolina, Chapel Hill 27514 and the SIDS Project Office, North Carolina Division of Health Services, Raleigh 27602.

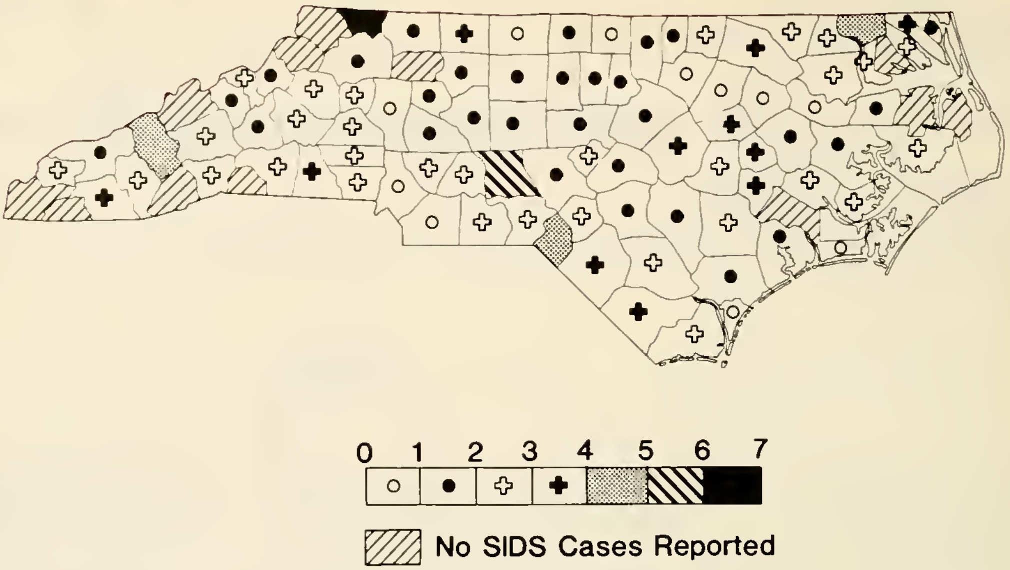

Figure 1. *County incidence of SIDS in North Carolina, 1979-1982. Incidence given as number of SIDS cases/1000 live births (n = 600).*

astroglial cell proliferation in the brain stem. This evidence suggests that some SIDS victims may experience repeated episodes of hypoxia prior to death. The mechanisms accounting for hypoxia are unclear; however, the leading hypothesis is that abnormalities in the neural regulation of respiratory and cardiovascular processes contribute to this episodic hypoxia.

Clinical support for the hypothesis that death may result from abnormalities in respiratory control comes from the observation that some SIDS victims experience repeated episodes of non-fatal apnea prior to death. Physiologic studies of infants who have survived episodes of apnea, so-called "near-miss SIDS" infants, have shown that as a group these infants have more frequent episodes of apnea, more periodic breathing, and may have an abnormal ventilatory response to administered CO_2. Future investigation of these infants, family members of SIDS victims, and animal models may ultimately yield information on specific abnormalities in respiratory control or reflex mechanisms peculiar to the developing nervous system that contribute to SIDS deaths.

Many other hypotheses explaining SIDS deaths have been proposed and later abandoned. Multiple mechanisms probably play a role in this syndrome. Current clinical and laboratory evidence suggests that gastroesophageal reflux, seizure disorders, and cardiac arrhythmias may be impor-

Table 1
Number of Sudden Infant Death Syndrome Deaths in North Carolina, 1979-1982*

	1979		1980		1981		1982		Total (1979-1982)	
Race/Sex	N†	Rate‡	N	Rate	N	Rate	N	Rate	N	Rate
White	63	1.1	88	1.5	82	1.4	78	1.3	311	1.33
Male	40	1.4	55	1.9	50	1.7	53	1.8	198	1.70
Female	23	0.8	33	1.2	32	1.2	25	0.9	113	1.03
Black	85	3.4	68	2.7	56	2.3	61	2.4	270	2.70
Male	51	4.1	35	2.8	26	2.1	38	3.0	150	3.00
Female	34	2.7	33	2.7	30	2.5	23	1.8	120	2.43
Indian	5	3.2	5	3.2	4	2.6	4	2.5	18	2.88
Male	4	4.9	3	3.9	2	2.6	2	2.5	11	3.48
Female	1	1.4	2	2.5	2	2.6	2	2.5	7	2.25
Total	153	1.8	161	1.9	142	1.7	144	1.7	599	1.78
Male	95	2.2	93	2.2	78	1.8	93	2.1	359	2.08
Female	58	1.4	68	1.6	64	1.6	50	1.2	240	1.45

* This table does not include one female infant of another race who died of SIDS in 1982.
†N = number of children who died of SIDS.
‡Rate = number of SIDS deaths/1000 live births.

tant contributing factors. The interested reader is referred to several excellent review articles for more comprehensive discussion.[3-7]

Near-Miss SIDS

The term "near-miss SIDS" has been applied to infants who experience an episode of apnea with limpness, cyanosis, or pallor and respond to vigorous stimulation or resuscitation. The term "apnea of infancy" has been proposed as a more appropriate label since "near-miss SIDS" may imply a closer relationship to SIDS than can be substantiated. Nevertheless, infants presenting with apnea between one and four months of age are presumed to be a subset of the SIDS population with similar mechanisms accounting for non-fatal and fatal episodes. Extensive evaluation of these infants may uncover associated, treatable conditions, some of which are listed in table 2. Approximately 40-50% of these infants will have subsequent episodes of apnea requiring intervention, often recurring during the stress associated with infections or immunizations.[8, 9] Available information suggests that 5-10% of these infants may ultimately die of SIDS, even when placed on home monitors.[9]

Management of SIDS and Apnea of Infancy

The medical management of a suspected SIDS episode should involve careful documentation of historical events and a detailed postmortem physical examination. Referral to the North Carolina Medical Examiners System for an autopsy is required for any unexplained infant death. The impact of an unexpected infant death can be devastating to families. Health professionals should communicate in a non-threatening manner, attempting to relieve any perceived family guilt. A timely conference to interpret autopsy findings is essential. Siblings and other caretakers should be included in modified sessions. Additional family support can be provided by the county SIDS grief counselor, a health professional specifically trained in the epidemiologic, medical, and psychosocial aspects of SIDS. This person's role is to provide families with information about SIDS, assist with the interpretation of autopsy findings, and facilitate the grieving process. SIDS parent support groups are also available in some counties. Information about county grief counselors can be obtained through the SIDS Project Office, Maternal and Child Health Branch, North Carolina Division of Health Services, PO Box 2091, Raleigh, North Carolina 27602 (1/800/662-7030).

Table 2
Disorders Associated with Apnea of Infancy

1. Infectious
    - Meningitis
    - Bronchiolitis
    - Pneumonia
    - Sepsis
2. Neurologic
    - Seizures
    - Intraventricular hemorrhage
    - Central alveolar hypoventilation
3. Respiratory
    - Obstructive lesions
4. Cardiovascular
    - Arrhythmias
    - Vascular rings
5. Gastrointestinal
    - Gastroesophageal reflux
6. Metabolic
    - Electrolyte imbalance
    - Metabolic acidosis
    - Hypoglycemia
    - Hypocalcemia
7. Other
    - Anemia
    - Prematurity
    - Idiopathic

The evaluation of an infant with apnea begins with documentation of the events surrounding the apneic episode. Information concerning the length of apnea, associated color changes, relationship to feeding, observed vomiting, potential seizure activity, other unusual symptoms, and the nature of resuscitative efforts should be sought specifically. The infant should be hospitalized for cardiorespiratory monitoring and evaluated for potentially treatable disorders as previously mentioned. Referral to a regional medical center is often needed for diagnostic studies and initiation of therapy.

Useful therapies for these infants may include: cardiac drugs, seizure medications, respiratory stimulants, therapy for gastroesophageal reflux, and surgery in selected cases. In some cases, no explanation for the episode will be discovered and home monitoring may be offered as a method of alerting parents to the occurrence of apnea or bradycardia so that intervention can be initiated promptly. In situations where the basis of an apneic event is better understood, home monitoring may be a useful adjunct to other therapeutic measures.

The success of a home monitoring program depends on appropriate parental education in the use of the monitor and infant cardiopulmonary resuscitation, provision of psychosocial support to the families, and assurance of appropriate continuing medical care. Home monitoring is usually continued until the infant has had two months without apnea alarms and is six months of age. Although appropriate studies have not been done to demonstrate that home monitoring reduces mortality, many authorities believe that the high rate of recurrence of apnea requiring intervention and subsequent SIDS deaths in this population justify the use of home monitoring until more specific therapy is available.

Home monitoring programs are available in most regional referral centers in North Carolina. Many private practitioners are also initiating home monitoring services. Data from companies supplying home monitoring services suggest that approximately 230 infants were monitored for apnea during 1983 in North Carolina.* This figure does not include otherwise well infants monitored as siblings of SIDS victims and may not include a small number of infants monitored with community-owned monitors.

---

* Data concerning monitored infants were obtained from the following: physicians and suppliers of home monitoring services: Cindy Lively, M.D., Bowman Gray School of Medicine, Winston-Salem; Alexander Spock, M.D., Duke University, Durham; Ross Vaughn, M.D., Wake Medical Center, Raleigh; John Wimmer, M.D., East Carolina University, Greenville; Charles Yoder, M.D., Asheville Neonatology, Asheville; Debbie Brookshire, Travenol Home Respiratory Services, Charlotte; Steve Chaucer, Medicare Supply Company, Durham; Jeff Jenkins, Glasrock Home Health Care, Raleigh; Steve Murtola, Ambulatory Services, Asheville; Matthew Recchio, Northwest Home Care, Winston-Salem; and Dave Varner, Ambulatory Services, Charlotte.

Approximately 50% of these monitor referrals were made directly by private practitioners. The remainder were initiated by physicians in referral centers. The monthly charge for equipment and 24-hour service is about $240.00, a cost covered usually by major insurance carriers. Monitors for Medicaid patients can often be provided with the assistance of local home health agencies. We are not aware of any litigation in North Carolina concerning the use of home monitors.

Infants in the increased risk categories, such as siblings of SIDS victims and premature infants, pose special problems. At this time, no test is known which will identify infants most likely to die. The challenging care of these infants and their families involves medical evaluation of the infant, identification of family concerns, and judgment regarding the use of any therapeutic modality including home monitoring.

Conclusion

Although our understanding of the sudden infant death syndrome has increased in recent years, much remains to be learned about the etiology and ultimate prevention of these deaths. As professionals caring for families of SIDS victims and infants with apnea we need to remain aware of current concepts of pathogenesis and treatment and resources available in North Carolina to facilitate optimal care. Specialized centers for the care of infants with apnea are being developed in several major medical centers in North Carolina, as in other areas of the country. Professionals practicing neonatology, pulmonology, cardiology, gastroenterology, neurology and psychology/psychiatry are available to offer guidance in the specific evaluation and management of these infants.

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CONJOINT REPORT

North Carolina: The Health of Our State

Ronald H. Levine, M.D., M.P.H.

- *The State Health Director's annual report on the state of the health of the state.*

FIFTY years ago this week, Dr. I. H. Manning of Chapel Hill, then President of the N.C. Medical Society, opened the Society's annual meeting with these words: "The public health should be a matter of gravest concern to the medical profession. Prevention of disease is one of the marvelous accomplishments of modern medicine and a glorious task for the profession. A death from a preventable disease should be on our conscience." That abiding interest and concern of the medical profession for the public health manifests itself each year in its receipt of the statutorily-based Conjoint Report which I am privileged to present once again. As in the past, I will highlight one topic of special interest, this year infant mortality in North Carolina. Interestingly enough, Dr. George Cooper, the Director of Preventive Medicine in North Carolina in 1934, had, according to President Manning, "called attention of the profession to the high . . . infancy death rate in this state."

First, allow me to offer a brief review of accomplishments, problems and issues of the year past. Several significant events occurred that will have an impact on tuberculosis control in North Carolina. At the request of the Department of Human Resources, the General Assembly voted to close McCain Hospital as a tuberculosis sanatorium. Thus the last tuberculosis sanatorium in this state and one of the last in the nation is no more. Nearly one-half million dollars in resulting savings were appropriated to the Department to be used to support tuberculosis control services across North Carolina. As a result of this allocation, we are now providing financial assistance for inpatient care as well as tuberculosis casefinding and management in all 100 counties of the state. Additionally, a 25-bed facility for tuberculosis patients requiring convalescent care was opened on October 1, 1983 at Cherry Hospital in Goldsboro.

North Carolina's Highway Safety Program worked hand in hand with the Governor's Task Force on Drunk Driving, legislative committees and others in developing and implementing the Safe Roads Act of 1983. Approximately 1,600 chemical analysts were trained and certified during the period. Special courses were conducted for judges, district attorneys, law enforcement officials and others to orient them to the chemical test provisions of the new law. As the result of implementation of the new law, there has been a significant decrease in arrests for driving while impaired. However the use and abuse of alcohol continues to represent the most significant problem in highway safety. Although DWI arrests have decreased since implementation of the new law, this trend will certainly not be maintained without continuous efforts to keep the issue before the public.

Environmental health and sanitation issues continued to consume a major portion of our staff's efforts. Staff of the Solid and Hazardous Waste Management Branch inspected all seven hundred and thirty hazardous waste facilities to obtain compliance with North Carolina requirements. The Environmental Protection Agency has recently contracted with our agency to determine if there is a threat to the public health or the environment from five hundred and twenty old disposal sites that have been closed since November of 1980.

In response to an unusually large number of food poisoning outbreaks last year, special training sessions for sanitarians and food service personnel have been successful in emphasizing the need for better sanitation and foodhandling, particularly in feeding large gatherings of people. One area of continued concern is the increase of foodhandling activities in "supermarkets" (e.g., fresh squeezed orange juice, self-service salad bars, oysters in the shell, bulk foods, delis, etc.). A similar trend beginning with hot dogs, but leading to an unlimited menu, is occurring in convenience stores.

On the positive environmental side the "Temporary Opening" concept for shellfish growing waters has been expanded. This action, dependent upon the ability to detect transitory favorable climatic and bacteriologic conditions in marginal waters, has made many thousands of dollars' worth of shellfish available to the fishermen, yet without jeopardizing the health of the consumer. We continue, however, to face a proliferation of condominiums with on-site subsurface sewage systems in recreational areas. This, combined with marinas, etc., around sounds and estuaries, has greatly increased the potential for pollution of our shellfish waters.

In the area of dental health, 187 water systems serving 192 communities are now adjusting the fluoride content of their water supplies. Twenty-six additional towns are being served by naturally fluoridated water. In rural areas, one hundred thirty-five schools continue to provide fluoridated water for approximately 52,000 children. Over 383,000 children, grades K-8 in over 1,000 schools in 85 counties, participate in a weekly sodium fluoride mouth-rinse program. Eighty percent of these children reside in non-

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From the Division of Health Services, Raleigh 27602-2091.

fluoridated areas of the State. Finally, over 58,000 children were referred by state and local staff to dentists in private practice for dental care. On-going evaluative studies have continued to show that these fluoridation and screening efforts are paying major dividends in the decrease of dental disease in our children.

The Human Tissue Donation Program has continued its efforts to provide information to the public through printed materials distributed by the driver licensing system, by participation in health fairs, and the presentation of programs to church, school and community groups, and through radio, newspaper, and television interviews. Almost 8,000 North Carolinians are signing Uniform Donor Cards each month and having their driver licenses show their willingness to be donors. Our information indicates that only one percent of persons who sign donor cards will actually die under circumstances that will allow for the recovery and transplantation of organs or tissues. Thus, there is need to greatly increase the pool of willing donors and to increase the number of community hospitals willing to participate in organ recovery activities.

Updated cervical screening guidelines were distributed to all local health departments and selected providers. The major change in these guidelines is that all women with two consecutive Class II Pap smears suggestive of significant cellular atypia are to be referred for evaluation and follow-up. Any Class III smear suggestive of dysplasia is also recommended for referral. We anticipate the revised guidelines to result in a fourfold increase in the number of women referred to rostered physicians in the private sector for the primary evaluation of abnormal Pap smears.

North Carolina's immunization program continues to be among the most successful in the nation. Thanks to collaborative efforts of our practicing physicians, school officials, both public and private, and our local health departments, more than 99% of North Carolina's children enter school having completed their full basic series. We have not had a North Carolina child contract measles for more than two years.

As a lead-in to my discussion of infant mortality I would like to summarize some of our efforts and concerns regarding services to women and children:

- The Crippled Children's Program provided diagnosis and treatment services to more than 20,000 chronically ill children with the cooperation and participation of more than 700 rostered physician specialists across the state.
- Our Developmental Evaluation Centers provided inter-disciplinary diagnostic service to 25,000 multi-handicapped children referred by private physicians and health departments.
- 96,000 low income pregnant women and babies in North Carolina are receiving physician prescribed protein supplementation via our hugely successful WIC Program.
- The Maternal and Child Health Branch supported prenatal clinics in 89 counties via the health department and in two additional counties via the local hospital. Approximately 15,000 indigent women were served by these clinics thanks in major part to the private practicing physicians who provide this care for next to no remuneration. In addition, almost 3,600 high-risk indigent women were served in special regional high-risk maternity clinics.

However, contrasting with these achievements we face some troubling challenges. Among them:

- New technologies, such as transplantation, bring the dilemma of remarkable health outcomes, but at startling costs. The Crippled Children's Program becomes a focus for this question of outcome versus costs — a topic of concern to the entire medical community. (One liver transplant versus how many strabismus corrections in children of low income families.) Is it any wonder that the field of medical ethics is burgeoning?
- Our Nutrition and Dietary Services Program is profoundly troubled and concerned with potentially dangerous and widespread food faddism and nutrition misinformation.

Let us turn now to a consideration of infant mortality in North Carolina. This health issue has received great attention and concern from individuals in health care and government at least since the early 1900s. In 1914, North Carolina's infant mortality rate was 90.3 deaths per 1,000 live births. This rate has thankfully declined over the decades. In 1970, our state's rate was 24.1 and in 1980 it was 14.1 showing a *rapid* decline of 41% over the decade.

However, our most recent rates have been 13.2 in 1981 and 13.7 in 1982. This represents a perplexing, though limited, increase in infant death in our state. It has occurred simultaneously with a period of unusual economic upset and, as such, has been the subject of much inquiry within our Division and elsewhere. In response to a request by the Governor, the State Center for Health Statistics, the Maternal and Child Care Section and a group of medical and health department leaders have made a detailed assessment of the recent increase in infant mortality. During the analysis, certain questions were raised and the answers developed as follows:

Is there a particular group of North Carolinians who appear to have experienced the greatest increase in mortality from 1981 to 1982?

Yes, certain subgroups of our citizens are affected, as follows:

- The increase in infant deaths from 1981 to 1982 occurred in *nonwhite* infants under 28 days of life (neonatal deaths). This nonwhite neonatal death increase was larger than would have been expected for the observed increase in nonwhite births and was clearly statistically significant.
- Detailed analysis of the numbers and rates for nonwhite neonatal deaths revealed increases among women who were
  - —ages 18 and above, with peak increases at ages 18 and 19;
  - —residents of urban areas, with peak increases in the biggest cities;
  - —delivered in our most capable medical centers, with peak increases at level III hospitals;

—of educational levels of twelfth grade or more.

- Of additional interest is that, while overall white neonatal mortality changed little, that finding concealed some increase in white neonatal deaths for mothers ages 20 to 24. All other white mothers enjoyed declines in neonatal deaths.

Did premature birth play a role in the nonwhite neonatal death increase?

Yes, prematurity did increase as follows:

- The percent of all nonwhite births with birthweights under 5½ pounds increased for nonwhite women from 11.8 in 1981 to 12.1 in 1982. In addition, the percent of all nonwhite births with birthweights under 3½ pounds increased from 2.4 in 1981 to 2.5 in 1982. This was especially true of extremely low weight infants in our big cities and our level III hospitals.
- In addition, there was an increase in neonatal deaths due to causes of death related to prematurity. Examples of these causes include extreme prematurity, hyaline membrane disease and multiple pregnancy.

Did birth defects play a role in the nonwhite neonatal death increase?

Yes, changes in deaths due to birth defects were as follows:

- There was an increase of 25 nonwhite deaths beyond expected due to birth defects. The largest proportion of these increases occurred in babies who were not premature to any great degree. No clustering in time or geographic location was evident in this group.
- Heart and blood vessel system abnormalities showed the most prominent increases.
- The increases in birth defects overall explained about as much excess mortality as the increase in deaths due to prematurity causes.

Did changes in the amount of prenatal care play a role in the nonwhite neonatal death increase?

Yes, as follows:

- While overall earliness and frequency of prenatal care improved for nonwhites, that improvement concealed some declines in the adequacy of prenatal care among mothers who experienced an extremely low weight birth. Thus, although the availability of prenatal care may not have declined to nonwhite mothers, the ability of our highest risk mothers to obtain it may have diminished.

From these findings, the group of medical and health care leaders recommended that further assessment be conducted through a collaborative review of individual medical records. In the meantime, private and public health care providers should:

- Continue to reach out to as many pregnant women as possible to assure early and frequent prenatal visits and to achieve high quality prenatal care for them.
- Enhance our efforts to prevent premature births through a multifaceted approach:
  —Prevention of unwanted pregnancy
  —Prevention of preterm delivery through high-risk identification and special health care as indicated for those at risk
  —Maintenance of high quality care of prematurely born infants, and
  —Provision of information to the public regarding the importance of prenatal care and the prevention of prematurity

Dealing with the issue of congenital malformations must await further studies. Consideration is being given to the establishment of a birth defects registry for North Carolina.

Progress and significant accomplishments thus vie with new challenges and problems — the agony and the ecstasy of Public Health. Your State Health Director of 1934 was acutely aware of both. In that year, the agony prevailed since Dr. James Parrott was stricken to his bed on the eve of his Conjoint Report after, as he put it, answering "the annual roll call thirty-seven years without a break." Nevertheless, Dr. Parrott, described by George Cooper as "sick, tired and weary, yet full of gratitude to his fellow physicians and hope for the future," penned the 1934 Conjoint Report from his sick bed and insisted that it be read in Pinehurst the following day. It contained the following words: "The philosophy of public health is the philosophy of the physician — it is the philosophy of sacrifice and service. The Health Department is the crowning glory of the medical profession. It is theirs, not by accident of discovery or the broad sword of gory conquest, but by the divine right of creation to be administered for the public good and for the public weal alone. It is the outstanding contribution of the physicians to the civilization of the commonwealth. I gain courage and take new hope when I am reminded that there are thousands of people alive today and enjoying life's richest blessings, and thousands of homes preserved that otherwise would have been destroyed were it not for the services which the public health department and doctors of North Carolina have rendered."

These words were spoken on May 2, 1934. They hold true on May 4, 1984. When officials from other states, with no little envy, sing the praises of North Carolina's public health system and its accomplishments, knowingly or not they laud its creator, nourisher and partner, the assembly of practicing physicians of this great state.

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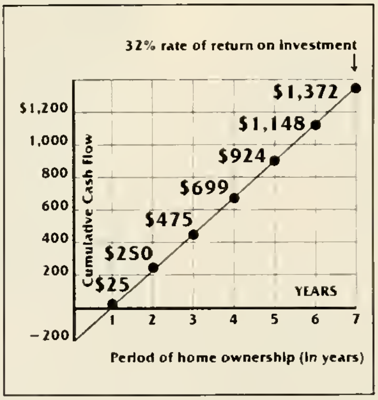

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PHARMACOTHERAPY

Drug Therapy of Systemic Fungal Infections, Part II

Mark Gross, Pharm.D.

Miconazole (Monistat IV)

Another imidazole derivative for IV or topical use, miconazole has been used for a variety of systemic mycoses yet it is considered a second-line agent for systemic use despite frequent success when administered topically. This is because experience with the drug is limited even with many infectious disease consultants. Susceptible species include *Candida, Cryptococcus, Coccidioides immitis, Pseudoallescheria boydii,* and others.[3, 31] It is the drug of choice only for serious *P. boydii* infections. Like ketoconazole, miconazole is probably a fungistatic, suppressive agent that can effect a cure in disseminated mycoses only after long durations of treatment. However, it demonstrates more significant toxicities than ketoconazole. In the treatment of candidiasis, miconazole has been used with mixed results. Although thrush and esophagitis can be treated successfully, systemic candidiasis may be more resistant to the drug. Using miconazole in 37 neutropenic cancer patients, Jordan et al reported a 41% cure rate.[33] Successful outcome, however, was temporally associated with recovery of neutrophils, making it unclear whether cure was due to the drug, white cell function, or both. Duration of treatment ranged from 5-29 days with daily doses of 1.8-3 g/day. Fischer et al used IV miconazole in five children with chronic mucocutaneous candidiasis who were unresponsive to topical or oral antifungals (nystatin, flucytosine, amphotericin B, iodochlorhydroxyquin) or who required repeated courses of amphotericin B.[34] No complete cures were achieved in five subjects, long term follow-up was not reported, and other antifungals were used concurrently. This is in contrast to the superb results with ketoconazole in this group of patients.

Some investigators have suggested that miconazole may be useful as an alternative to amphotericin and flucytosine in cryptococcal infections.[35] Although successful outcomes were reported, none of the patients were cured when treated with miconazole alone and it had to be given intrathecally in several cases. Graybill has suggested that miconazole be used adjunctively with amphotericin B. However, there may be some evidence for antagonism.[36] Until further evidence indicates otherwise, miconazole should be reserved as a broad spectrum, second-line drug for patients who cannot tolerate standard antifungal regimens.

Miconazole is eliminated similar to ketoconazole, primarily via the feces in both metabolized and unchanged forms.[40] This highly protein-bound drug (90%) shows two-phase elimination after IV infusions with a terminal half-life of 24 hours, peak levels of 2-9 mcg/ml, and volume of distribution of 20 L/kg.[40, 41] CSF penetration is extremely poor and intrathecal administration is usually required to achieve therapeutic concentrations.[40] Each dose of miconazole should be diluted in 200 cc of D_5W administered over one hour, and sites should be changed frequently to avoid phlebitis.[3] Dosing is usually on a TID schedule. Dosages reported range from 200-3600 mg/day, depending on the mycosis, and duration ranges from one to twenty weeks (see table I).[40] Reductions in dosing are not necessary for patients with renal disease. Competition between miconazole and other protein-bound drugs such as warfarin may potentiate their effects.[40]

Miconazole, like amphotericin B, may produce a severe anaphylactic response manifested by hypotension, arrhythmias, renal impairment, hyperkalemia, and metabolic acidosis after as little as 400 mg.[37] Therefore a test dose of no more than 200 mg should be given under the supervision of a physician.[38] Most of the adverse reactions associated with this drug are thought to be due to the castor oil vehicle in which miconazole was solubilized, "Cremaphor EL."[3] The vehicle can induce the release of histamine, resulting in severe pruritis unresponsive to antihistamines. It may also cause elevations in serum lipoproteins.[39] However, a new preparation has removed Cremaphor EL and replaced it with propylene glycol. No hepatic or renal toxicity has been associated with long-term use of miconazole, although transient elevations in liver enzymes are a rare occurrence.[3, 40]

Table 1
Range of Adult Doses of Miconazole

Organism	Dosage range (mg/d)	Duration of Successful tx (weeks)
Coccidioidomycosis	1800-3600	3 to more than 20
Cryptococcus	1200-2400	3 to more than 12
Candidiasis	600-1800	1 to more than 20
Paracocci.	200-1200	2 to more than 16
Dosing in children — 20-40mg/kg/d		

(source: ref. 39)

From the Department of Pharmacy, Duke University Medical Center, Durham 27710.

References available from the NCMJ editorial office.

Flucytosine (Ancobon)

Flucytosine is an antifungal that may be used alone or in combination with amphotericin B for some systemic mycoses. Unfortunately its use has been limited by the tendency of many species to develop resistance. Flucytosine (5-FC) functions by being selectively converted into 5-fluorouracil within the fungal cell and, except in concentrations greater than 100 mcg/ml, not in mammalian cells.[42] The drug is active against *Candida* species, *Torulopsis*, *Cryptococcus*, and chromomycosis.[43] The site of action is thought to be at both DNA and RNA synthetic pathways.[44]

5-FC is best known for its use in cryptococcal meningitis, either alone or in conjunction with amphotericin B. Although it has been shown to be curative as a single agent for cryptococcal meningitis, combination therapy is probably superior because of the shorter interval of treatment required and the greater efficacy against 5-FC resistant organisms.[16, 42] The incidence of 5-FC resistance may be 1-2% for cryptococcal species, as high as 50% for candidal species.[45] Since secondary resistance can develop during therapy, a conservative strategy would avoid the singular use of 5-FC for any mycosis. However, normally resistant pathogens may be susceptible in the bladder because of very high urinary concentrations and therefore 5-FC may be used alone for urinary candidiasis if one realizes potential problems. Amphotericin B and 5-FC have also been used empirically in aspergillus infections despite the lack of clinical studies confirming any clinical advantage to this combination.[3] Despite a scarcity of clinical data, 5-FC and amphotericin B may be used together for candidal infections. The two drugs have been found to have a slightly additive effect *in vivo* and *in vitro*.[46]

Table 2
Flucytosine Dosing in Renal Failure

Creatinine Clearance ml/min/1.73m^2	Dose mg/kg/day
Greater than 40	150
20-40	75
10-20	37.5
less than 10	measure serum drug levels

(source: ref. 2)

5-FC is 78-89% absorbed after oral administration. Normal subjects demonstrate an excretion half-life of 4.2 hours, and the drug is 90% excreted in the urine.[47] Following hemodialysis 20 mg/kg should be given to maintain steady state levels.[42] Patients with renal disease should receive reduced doses based on their creatinine clearance (see table 2). Ideal therapeutic levels lie between 50 and 100 mcg/ml, achievable with doses of 150 mg/kg/day in patients with normal renal function. CSF levels are 71-85% of serum levels following oral dosing.[47]

Most patients tolerate 5-FC without serious adverse

Table 3
Antifungal Therapies

	Uses	Regimen	Toxicity	Comments
Amphotericin B	Systemic Candidiasis Cryptococcosis (with 5-FC) Coccidioidomycosis Histoplasmosis Aspergilosis	1 mg IV test dose then 10 mg IV to 1 mg/kg/day maximum dose Increase by 5-10 mg/day	Nephrotoxicity Anemia Hypokalemia Hypomagnesemia Thrombocytopenia Immediate reactions: Anaphylaxis Shaking chills, Fevers	Avoid preparing in saline solutions Monitor: electrolytes, S_{cr}, Hgb, Hct, platelets.
Flucytosine (5-FC)	Fungal Urinary Tract Infections Candidiasis* Cryptococcosis Aspergilosis* Chromomycosis	100-150 mg/kg/day PO, q6h adjust dose in renal failure (see table 2)	Nausea, Vomiting, Leucopenia, Thrombocytopenia, GI irritation, Hepatic dysfunction	Serum levels greater than 100 mcg/ml associated with toxicity and systemic 5-FU effects.
Ketoconazole	Candidiasis† Cryptococcosis† Histoplasmosis† Blastomycosis† Chromomycosis†	200-600 mg/day PO (qd or bid) larger doses for severe infections	Hepatic dysfunction Nausea, vomiting, diarrhea, gynecomastia suppressed cortisol and testosterone levels	Avoid concomitant use of antacids or other anti-ulcer drugs. Best absorbed in acid stomach or with food.
Miconazole	*Pseudoallescheria* (Petriellidium) *boydii* Candidiasis‡ Cryptococcosis	200-3600 mg/day 200 mg test dose (see table 1)	"Cremaphor EL" vehicle: hyperlipidemia, anaphylaxis, pruritis, arrhythmias rare elevated liver function tests	Re-formulated vehicle may eliminate toxicities during administration.

* Used in combination with Amphotericin B with questionable efficacy
† For non-life threatening infections in patients with intact immune functions.
‡ Second-line therapy when Amphotericin B cannot be used.

effects, even in long dosing periods but its side effects can be serious. Most adverse effects involve irritation to the gastrointestinal tract, nausea, vomiting, and diarrhea.[42] Intestinal perforation is a rare complication.[43] Levels that consistently exceed 100 mcg/ml are associated with myelosuppression, pancytopenia, and hepatotoxicity possibly due to conversion to 5-fluorouracil in mammalian cells, and therefore such elevated levels should be avoided. 5-FC toxicity remains a problem in treating seriously ill patients and those with reduced renal function.

Amphotericin B Methyl Ester

Amphotericin B methyl ester was synthesized in an attempt to create a congener of amphotericin B which maintains its antifungal potency but lacks its nephrotoxicity. Early studies showed that amphotericin B methyl ester retained the anti-fungal activity of amphotericin B but nephrotoxicity was uncommon even at doses five times the normal amphotericin B concentration.[48] A recent study showed that severe neurological damage characterized by diffuse white matter degeneration occurred in human subjects, often leaving them with profound deficits.[49] It was theorized that impurities in amphotericin B methyl ester were responsible for this toxicity but this was disproven when similar reactions occurred with lots that were either 35% or 65% pure.[49] Leukoencephalopathy of the methyl ester compounds remains a concern and has delayed their development in clinical practice.

Conclusions

If used rationally, antifungal agents can effectively eradicate systemic fungal infections with a minimum of adverse reactions or toxicities (see table 3). Depending on the patient, a highly toxic fungicidal drug such as amphotericin B may not always be needed. If the patient is immunocompetent, adequately compliant, and has a pathogen which is susceptible to an oral agent such as ketoconazole, there is substantial evidence that prolonged (six months or more) suppressive therapy with this agent may be as effective as a course of intravenous therapy with amphotericin B so that significant toxicities may be avoided.[5, 7, 8] Conversely, an immunosuppressed patient with a life-threatening mycosis such as endocarditis or meningitis will need fungicidal therapy with one or two drugs, and severe toxicities may be inevitable. Despite recent advances in antifungal therapies, the chances of complete eradication of systemic fungal infections in an immunocompromised host remain poor since the immune system of the host plays such an important part in the development of disease. We have yet to consistently intervene successfully in this aspect of the host-parasite confrontation.

TOXIC ENCOUNTERS

St. Ronald's Ballet — Strychnine Poisoning

Ronald B. Mack, M.D.

[This treatise is not meant to be either sacred or profane. I am apologizing at the outset.]

MANY academic physicians allege that they eschew eponyms (repeat this rapidly six times), but I love them. In the June 1984 issue of the *Journal of Pediatrics* in the Letter to the Editor section, there is again a request to limit the use of eponyms.[1] Having a disease named after a person or persons seems perfectly delightful to me; it is so romantic, so heroic, so laudatory. I really believe that no one will ever name a disease after me so I decided to name one after myself — St. Ronald's Ballet. After you read this article, see if you don't agree.

I would guess that the naming of diseases for saints began during the period of medieval medicine which covers the period between 500 AD and 1500 AD.[2] Apparently in the Middle Ages the physicians of the time had to try to combine the pagan medical traditions of the invading barbarians with the classical traditions of the now destroyed Roman Empire and the Christian religion.

Medieval medicine is divided into two periods: the early period known as the era of *monastic medicine* and the late period referred to as the period of *scholastic medicine*. In the monastic period, as the name implies, monks played a major role in the providing of medical care and in the composition of medical texts (the printing press after all would not be available until 1448 when Johann Gutenberg put it together and the photocopy process did not occur until our historical period). In this early medieval period, the Church, allegedly, emphasized interest in the soul as opposed to maladies of the body. Christianity, early on, apparently had its own theory of disease: either disease was punishment for sins, or possession by the devil (I still believe this but don't tell anybody, please!!), or the result of witchcraft. Therefore, their treatment consisted of prayer, penitence and the assistance of saints. The Council of Clermont in 1130 forbade monks to practice medicine and this job now became the province of the secular clergy, i.e., the non-monastic priests. Scholastic medieval medicine which occurred in the second half of the Middle Ages was merely a repetition of the Greek Medicine period (500 BC to 500 AD) and its theories, plus many elements of supernaturalism including the invocation of numerous saints specializing in specific diseases. My colleague, Dr. Robert W. Prichard of Bowman Gray School of Medicine — an esteemed medical historian as well as an esteemed pathologist — suggests that another element in the naming of some diseases after saints is that some of the requirements of sainthood mandated the performance of miracles which certainly could have been observed to occur in a medical context in many instances.

The list of diseases named for saints is quite long indeed. The best known to most of us is St. Vitus Dance AKA Syndenham's Chorea (two separate eponyms). Chorea is such a peculiar phenomenon that in the Middle Ages it was also known as St. Anthony's dance, St. Guy's dance, St. Modestus' dance and originally St. John's dance. The term dance in these eponyms seems to be related to the *dancing mania*, a really unusual psychic aberration which caused epidemics whereby literally thousands of men and women danced till they collapsed from physical exhaustion (today they are called "break dancers"). St. Anthony was really very lucky, he had three diseases named for him: chorea (St. Anthony's dance), erysipelas (St. Anthony's fire) and ergotism (also St. Anthony's fire). Hemorrhoids, known as St. Fiacre's disease, should properly be called St. Anthony's fire as well — at least in my opinion.

In the name of St. Sebastian (the plague) where is all this leading to? My real subject today is *strychnine* poisoning. We recently had a young adult patient who was given some strychnine (without requesting it) in his regular supply of cocaine. He entered our emergency room with "convulsions." My interest was piqued because this poison is a fascinating and old enemy. Strychnine is an alkaloid extracted from the seeds of the Strychnos nux-vomica tree and has been used since the 16th century to kill rodents and also used in medical therapy although it has no known therapeutic value. This substance, a white, bitter-tasting, crystalline, odorless, colorless alkaloid, is available in dozens of products, even as we speak — primarily rodenticides but also veterinary products, and laxatives, tonics, or stimulants for human use and of course an adulterant of illicit drugs of abuse. One of my colleagues remarked that in the spring, when he was a young lad, he was given nux-vomica as a tonic.

The pharmacokinetics of strychnine are fairly well defined. Absorption of strychnine occurs quite rapidly from the GI tract as well as the nasal mucosa (the latter makes it especially inviting for those who adulterate cocaine). Furthermore, it is rapidly absorbed from subcutaneous or IM injection. This drug is apparently not bound to protein to any important degree and thus rapidly enters the brain and cord, liver and kidneys. Most of the strychnine is metabolized by microsomal enzymes in the liver. Within minutes after an ingested dose strychnine can be detected in the urine. By St. Giles (leprosy) and St. Hubert (rabies),

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strychnine is a weird toxin. Apparently this drug produces its clinical effects by competitively blocking the postsynaptic receptor sites for the inhibitory transmitter *glycine*. Now glycine is the big deal here as it is thought to be the primary inhibitory transmitter in the spinal cord and to a lesser extent in the brain stem. Glycine is sort of like my Dad's cousin Charlie; during Prohibition his job was to keep the operation quiet and running smoothly. If Charlie was neutralized all hell broke loose. When an overdose of strychnine is taken in concentrations high enough to compete with glycine, the inhibition of motor neuron acitvity is decreased and forceful muscle contractions occur. Although this toxin excites all parts of the CNS the important scenario from the clinician's point of view is its effect on the spinal cord motor neurons especially at the postsynaptic receptor sites of the ventral horn motor neurons.

The lethal dose of strychnine in human beings is estimated to be about 15-30 mg, but deaths have been reported from much less. The onset of symptoms occurs quite rapidly, usually within 15-30 minutes after ingestion, and relate entirely to the blockage of the glycine receptors as has been stated. (You know, that is so true. As a teenager I remember my mother telling me not to inhibit my glycine.) Early on, the patient experiences a feeling of restlessness and anxiety with a heightened sensory awareness of sight and sound, not to mention muscle tightness. If a physical exam is performed at this time you might notice hyperreflexia and twitching of small muscle groups. With larger doses there is rapid progression to the so-called strychnine "convulsions" which are indeed horrific. These convulsions consist of generalized symmetrical tonic extensor muscle spasms with opisthotonus (hence, St. Ronald's Ballet). The very powerful dramatic extensor spasms are produced by the specific blockade of reciprocal inhibition among antagonistic muscle groups (I knew it all the time!!) and are really quite dissimilar to the classic tonic-clonic seizures arising from a seizure focus in the cerebral cortex. Lethal asphyxia can occur secondary to intense spasm of the thoracic and abdominal muscles and, of course, the diaphragm. The weird part of this clinical picture is the fact that even minimal sensory stimuli may set off violent muscle contractions lasting 30-120 seconds or more [For St. Martin's (alcoholism) and St. Zachary's (mutism) sake, don't even sneeze in the patient's presence.]. The "convulsions," trismus, risus sardonicus and opisthotonus in a conscious patient makes this clinical picture an unforgettable event for all concerned. The miserable patient can experience these abnormal clinical features from 2 hours to 2 or 3 days and (with adequate oxygenation) remains conscious. Between the "attacks" complete muscular relaxation occurs for 5 to 15 minutes or more but another attack ensues from any external sensory stimulus when the hyperexcitable state returns. When death occurs it does so within 1 to 3 hours after the strychnine enters the body; survival is very good (usually without important sequellae) if the patient "makes it" beyond the first 5 to 6 hours.

As you probably can imagine, there are multiple complications as a result of the violent repetitive muscle contractions; prominent adverse clinical features must therefore include *rhabdomyolysis* and subsequent myoglobinuria, *lactic acidosis* with markedly elevated lactate levels, and unbelievably depressed arterial pH levels and *hyperthermia*. The rhabdomyolysis occurs as a result of the muscle cell injury and causes elevated levels of muscle enzymes, e.g., CPK, LDH, SGOT. The myoglobinuria that forms as a result of this muscle injury can and does lead to renal failure. Lactic acidosis is probably the most common cause of metabolic acidosis that you will run into in an Emergency Room and quite readily occurs with seizures that are of cortical or noncortical etiology as well as with maximal exercise. The remarkable muscle activity that occurs in strychnine poisoning causes heat production to proceed at a rate faster than the heat loss and hyperthermia is the result.

Well, by St. Ignatius (pellagra) and St. Appolonia (toothache) how do you diagnose and treat such an awesome encounter of the toxic kind? The history and physical remain the best diagnostic tools available. You must consider strychnine poisoning in any unfortunate patient who retains consciousness during what appears to be violent convulsions. You can detect strychnine via thin layer or paper chromatography but these determinations will most likely not help you at the bedside. The management of a patient intoxicated by strychnine obviously mandates suppression of the convulsions, support of the cardiorespiratory system and correction of the acid-base imbalance. It would be wonderful if administering *glycine* would suppress the convulsions but so far this chemical has not been very useful at the bedside. The method of choice in the control of the seizures has not yet been written in stone but many authorities recommend using intravenous diazepam initially. This benzodiazepine is felt to be a noncompetitive antagonist to strychnine. If diazepam fails to quell this disaster, even with large doses, then cerebral anesthesia using barbiturates should be considered; some authors would also add pancuronium to this regimen, to produce muscle paralysis. You may need to combat the lactic acidosis with sodium bicarbonate, but the biochemical abnormality can improve rapidly with cessation of muscle spasm activity and ventilatory support. Rhabdomyolysis may not lead to precipitation of myoglobin in some patients if the urine is rendered alkaline. Hyperthermia should resolve with elimination of muscle spasms plus the use of cooling blankets and/or iced saline gastric lavage. Fluid diuresis or dialysis do not seem to be of value in this poisoning and should not be used.

Why St. Ronald's Ballet you ask, why not St. Ronald's Dance? Well, you must believe I asked but the Dance was already taken. With your permission I would like to name a condition after my grandson, St. Jeb (carrying a stuffed animal to the awarding of your Nobel prize).

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Goosey Patients: Relationship to Jumping Frenchmen, Myriachit, Latah and Tic Convulsif

E. Wayne Massey, M.D.

● *Goosey patients are unusual, but not rare. Similar conditions have been described in other cultures for centuries.*

"GOOSEY people are not rare and we should all think twice before goosing someone."[1] Patients with exaggerated startle response have been emphasized for many years, in fact for centuries.

Latah in Malaysia, Piblokto in the Arctic, and Amok in Malaysia all involve reflex responses and have been known for centuries.[2] Myriachit, described in Siberia before the 1880s, the jumping Frenchmen of Maine in the 1880s, and Tic Convulsif in the 1880s also involve involuntary movements of jerking, jumping or startle.

In 1980, J. E. Hardison[1] reported several patients from the southern United States who had a startle response and who had been called "goosey." Goosey is defined as "susceptible to or reacting strongly."

A startle response is an uncontrolled jerk or jumping motion in response to an unexpected strike. It may be a form of myoclonus which is involuntary shock-like contractions of one or more muscles which may be restricted or occur multifocally throughout the body or even displace the entire body. Myoclonus often follows a repetitive pattern and is usually irregular, although sometimes there is a rhythm. Jumping, startle and goosey seem to be similar. They cannot be self-induced.

Dr. Hardison referred to his experience at age 17 when his girlfriend confided to him that her mother was goosey. In addition, his father had told him of two goosey boys in a small town in North Carolina where his father was raised. He referred to another case from Tennessee and mentioned several cases seen by his fellow physicians over the years.[1]

Present Cases

Two brothers seen at Duke Hospital, age 23 and 27, have manifested jumping or startling in response to minimal stimuli. Both patients had experienced this from childhood and were born and raised in the southwestern part of North Carolina. Although adults when examined, both stated that they had been goosey since early childhood. They demonstrated a marked or violent jump in response to sudden noise or being startled. These did not occur spontaneously and there was no loss of consciousness. Both patients had a normal neurological examination. Neither manifested coprolalia but both had experienced echolalia on occasion. These patients had been termed goosey by their friends and relatives and fit the pattern described in other North Carolina patients.[3]

Discussion

This syndrome seems to be related to other forms of startling that have been described. These include the syndrome of Jumping Frenchmen of Maine, emphasized by Beard in 1880, of Myriachit, described by Hammond in 1884, of Latah, described in the Malayan literature as early as the 14th century, and similar to Tic Convulsif as de-

Figure 1. *Dr. G. Gilles de la Tourette. Photo from the National Library of Medicine.*

From the Division of Neurology, Duke University Medical Center, Durham 27710.

Figure 2. *Dr. George M. Beard. Photo from the National Library of Medicine.*

Figure 3. *Dr. William A. Hammond. Photo from the National Library of Medicine.*

scribed by Gilles de la Tourette in 1884 (figure 1). Echolalia, repetition of words just spoken, or coprolalia, uncontrollable use of obscene language, may occur in these disorders which begin in childhood, affect both men and women, and may be hereditary (see table 1).

In 1880 at the Sixth Annual Meeting of the American Neurological Association, Dr. George Beard (figure 2) presented a paper on "Experiments with the Jumpers or Jumping Frenchmen of Maine,"[4] describing subjects of French Canadian extraction, "mostly lumberjacks," who could not restrain from jerking or jumping in response to a sudden strike or kick. They lived in the Moosehead Lake region of Maine.[5] When two "jumpers" were close together they struck each other simultaneously with severe blows associated with startle. Some of the patients had echolalia and some responded automatically to a loud command by repeating the command and executing the order even though it may have been dangerous or humiliating to them.

Dr. William Hammond (figure 3) described Myriachit in 1884[6] with an epidemic of "jumpers" in Siberia (myriachit means "to act foolishly"); it had been described earlier in the foreign literature.[7] Echolalia and echopraxia, pathological repetition of the acts of other people, sometimes occurred in an automatically obeyed command.

Table 1
Comparison of Jumping Frenchmen, Myriachit, Latah, Goosey, Tic Convulsif

Syndrome	Jumping	Latah	Myriachit	Goosey	Tic Convulsif
Year reported	1880	1500's	1884	1980	1825
Sex	M	F	M, F	M, F	M, F
Onset	Child	Adult	Epidemic	Child	Child
Familial	+	?	+	+	?
Geography	Frenchmen	East; Africa	Siberia	Southern U.S.A.	Universal
Neurological findings	0	0	+	0	+
Length of attack	Seconds	Seconds — Hours	Hours	Seconds	Seconds
Imitate	+	0	0	0	0
Startle	+	+	+	+	0 (Spontaneous)
Echolalia/coprolalia	+/−	+/+	+/−	+/−	+/+

The movements are similar in each; resolution is the same; loss of consciousness does not occur in any.

Latah has occurred in women in primitive societies for centuries; they manifested immediate and accurate repetition of a noise, music or gesture, often associated with coprolalia.[8] Both these entities may be hereditary and the etiology is unknown.

The older neurological literature assumes the similarity of jumping to Tic Convulsif of Gilles de la Tourette syndrome.[9] Although this lifelong syndrome begins in childhood, it produces spontaneous movements that are not triggered by startle but are associated with coprolalia.[2] However, it is unlikely that these entities are related.[3]

Dr. Harold Stevens[3] has reported two additional cases of "jumpers" in 1965. His second patient was a 52-year-old woman who had a niece with a similar affliction. Both were of Protestant-Scotch-Irish-German extraction and were reared in North Carolina.

Startle responses are unusual but certainly not rare. They occur in various cultures and possibly are similar (despite the varied labels) although not identical in clinical characteristics. Goosey, in North Carolina, seems to be similar to startle responses described in our culture. Startle cannot be self-induced. It can be suppressed in many people, however, when they are properly warned.

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LEARNING WITHOUT WORDS

Down the Wrong Garden Path

Ronald B. Easley, M.D., Ph.D.

• *Expecting all four cardinal features of Parkinsonism before suspecting the presence of Parkinson's disease can lead down the wrong garden path.*

THERE are four cardinal features that come to mind when I am considering a diagnosis of Parkinsonism: 4 cps tremor at rest, muscular rigidity and mask-like facies, bradykinesia with a flexed and shuffling gait, and postural instability. Intellect, power, cranial nerve function and sensation are unaltered (table 1). I have been down the wrong garden path on two occasions during the past year for expecting all of the above features before suspecting the presence of Parkinson's disease. The following case report will illustrate this basic misconception.

E.K. is a 66-year-old woman who had been gainfully employed until retirement at age 65. She appeared on three occasions to the emergency department with symptoms suggestive of acute panic episodes. A serum thyroxine level obtained on her last ED visit was 12.2 mcg/dl. On examination she appeared fearful with a resting tachycardia, fine intention tremor of the outstretched hands, and hesitant speech. She had a stooped posture and expressionless facial appearance. There was a history of recent insomnia and loss of appetite. She had a slow but stable gait, and rapid alternating maneuvers were poorly performed. A TRH stimulation test elicited a normal TSH response.

She became uncooperative and demanding at home and her family decided to place her in a convalescent center. Her mobility continued to deteriorate to wheelchair confinement. She was accused of faking her disability by family as well as nursing assistants. Examination two months later disclosed muscular rigidity, hypomimia and decreased blink frequency, fine intention tremor and hesitant speech. The proverbial bolt of lightning finally struck and she was placed on Carbidopa. Bradykinesis and muscular rigidity dissipated and she is now living independently.

Rest tremor is typically the first symptom of Parkinson's disease. Perhaps 20-30% of patients, however, will not develop the rest tremor until late in the disease.[1] In 1817 James Parkinson stated "so slight and nearly imperceptible are the first inroads of this malady, and so extremely slow is its progress, that it rarely happens that the patient can form any recollection of the precise period of its commencement."[2]

Slowness of movement and expressionless facial appearance are often interpreted as concomitants of depression. Yet a depressed person can be forced into rapid movement; the Parkinsonian will stumble or fall. And don't be misled by the presence of an action tremor; 10-20% of Parkinsonians will have this when asked to posture.

TABLE 1
Signs of Parkinsonism

Typical Features

4cps tremor at rest
Muscular rigidity (cogwheel)
Slowness of movement
Postural instability
Mask-like facies

Less Typical Features

8-12cps action tremor
Distal dystonic movements
Impaired upward gaze
Hesitant speech
Slowness of chewing and swallowing

Preserved Functions

Power
Intellect
Cranial nerve function
Sensation

Parkinson's disease results from a deficiency of dopamine in the caudate and putamen (striatum). The pathologic hallmark is cytoplasmic inclusion bodies (lewy bodies) in the pigmented neurons of the substantia nigra. Dopamine regulates intracellular cyclic AMP in the striatal neurons. These events modify input into the pallidum, ventral lateral thalamus, and subsequently the motor cortex. It is still debated whether treatment of Parkinson's disease alters its mortality rate. Some studies demonstrate an incidence of dementia when high dose Levodopa is used.[3] Perhaps the addition of a dopa decarboxylase inhibitor has reduced this complication. The improvement in the quality of life with treatment remains undebatable.

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From the Piedmont Diagnostic Clinic, 6005 Russell Road, Durham 27712.

LEARNING WITHOUT WORDS

Thyroid Malignancy Masquerading as Thyroiditis

Warner M. Burch, M.D.

• *Two cases of thyroid cancer that appeared at first to be thyroiditis.*

I RECENTLY cared for two patients who taught me that thyroid cancer may masquerade as thyroiditis. Both patients were initially thought to have thyroiditis in that each had a sudden onset of thyroid enlargement and a low radionuclide thyroidal uptake. What was unusual about these patients was that their clinical course was atypical for a benign self-limiting process and led to further investigations.

Case Presentations

Patient 1

A 16-year-old girl noticed swelling in her anterior neck, anxiousness, and inability to sleep one month after an upper respiratory infection. She denied any fever, palpitations, weight loss, neck pain, or unusual exposure to X-irradiation. Her maternal grandmother had a goiter. On physical examination, the pulse was 140; the left lobe of the thyroid was smooth, non-tender, and measured 4 cm in width and 5 cm in height; the right lobe and isthmus were just palpable but not enlarged. No other abnormalities were noted.

Serum thyroxine was 13 μg/dl (normal 5-12); T_3U, 54% (normal 34-45); and thyroidal uptake of technetium-99m pertechnetate was low without any focal abnormality. Her physician referred her to me. Two weeks later, she appeared to be euthyroid and her serum thyroxine was 6.3 μg/dl; T_3U, 46%; and 24-hr thyroidal I-131 uptake 1%, a value too low for accurate scanning. The sedimentation rate was 10 mm/hr; thyroid microsomal and thyroglobulin antibodies were negative. All of these findings were consistent with painless thyroiditis (it is relative common to see transient hyperthyroidism in this entity). I prescribed aspirin 600 mg qid and her symptoms abated over the next few weeks.

The enlarged left lobe did not regress over the next ten months. This worried me since the gland should have spontaneously decreased in size over this interval if painless thyroiditis was the cause. Other benign enlargement such as focal Hashimoto's thyroiditis seemed less likely with absence of thyroid microsomal antibodies. I performed fine needle aspiration biopsy of the thyroid.[1] The aspirate revealed changes consistent with papillary thyroid carcinoma. There were varying size nuclei, increased gran-

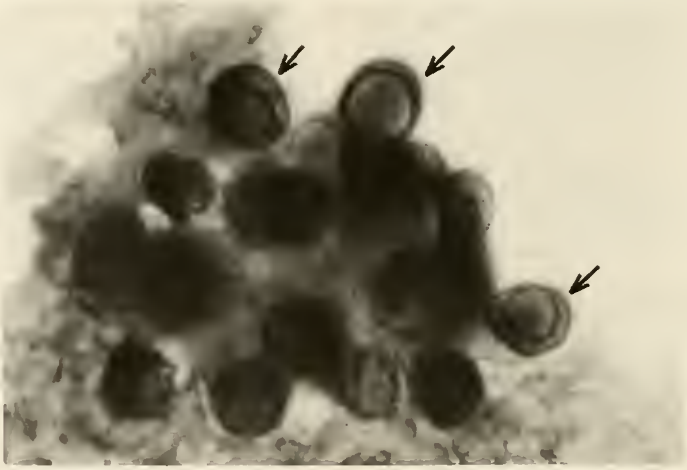

Figure 1. *Photomicrograph of fine needle thyroid aspirate from Patient 1. The arrows mark three Orphan Annie cells. The appearance is due to large round inclusions that are actually an invagination of the cell membrane. Finding these cells strongly suggests thyroid carcinoma.*

From the Department of Medicine, Duke University Medical Center, Durham 27710.

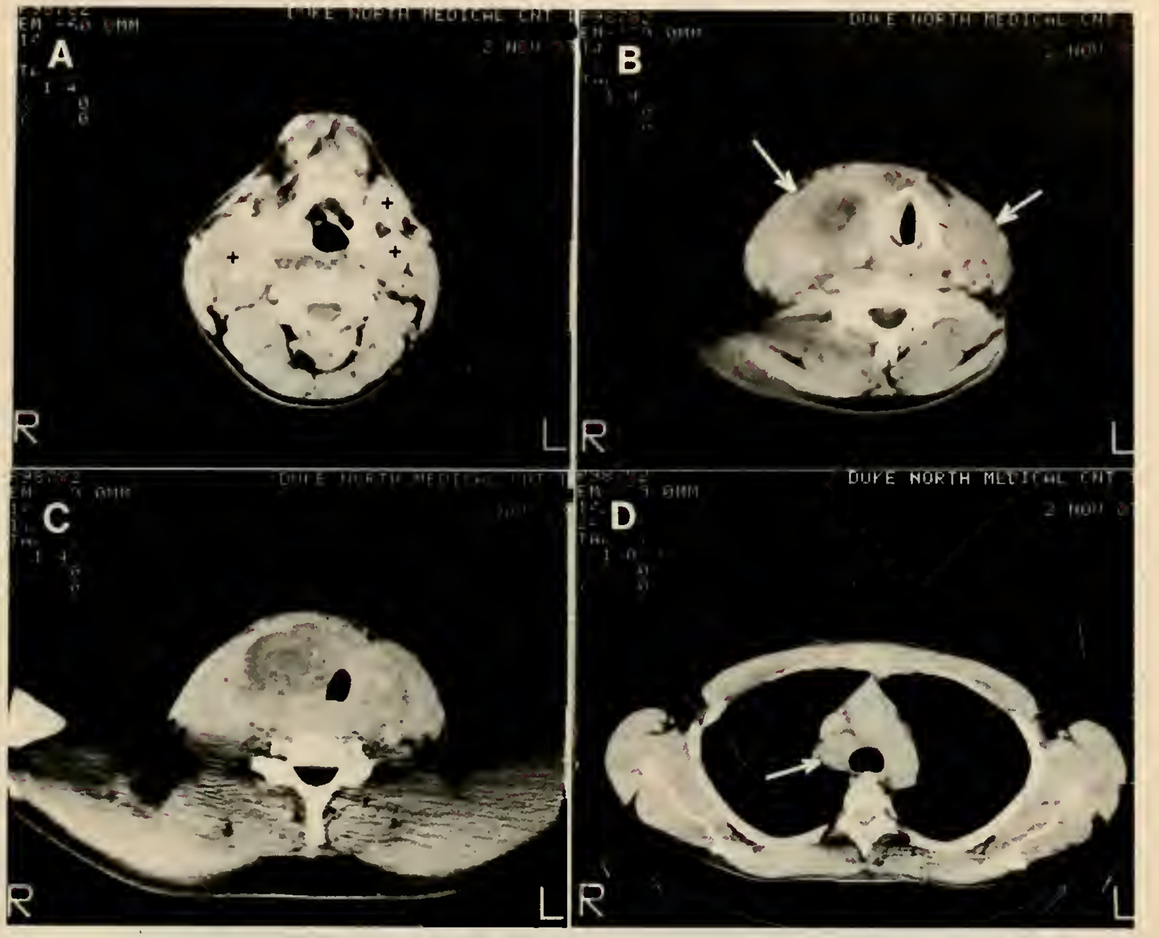

Figure 2. *Computerized tomographic scan of the neck and upper thorax of Patient 2. The sequence begins in the upper neck just inferior to the mandible* (A), *progresses inferiorly to the level of the larynx (B), then to the thyroid below the larynx (C), and finally to the level of the carina in the chest* (D). (A) *Note large masses (marked with +), presumably lymph nodes.* (B) *The arrows point to the thyroid lobes, which are greatly enlarged. The right lobe contains a hypodense area and displaces the larynx to the left.* (C) *The massive increase in thyroid size including isthmus has compromised the tracheal aperture.* (D) *The mass (marked with arrow) extends down the trachea to the level of the carina.*

ularity of nuclear chromatin, and cells with a washed-out nuclear appearance — so called Orphan Annie cells (see figure 1). These cells are often found in aspirates of papillary thyroid carcinoma and though not diagnostic are suggestive of thyroid cancer. At surgery, papillary thyroid carcinoma involved the entire left lobe and several regional lymph nodes contained tumor. Treatment consisted of total thyroidectomy, postoperative thyroidal ablation with radioactive iodine, and thyroid replacement. Two years following surgery, she remains healthy and the total body I-131 scan continues to be negative.

Patient 2

A 27-year-old man presented to his physician with sudden onset of pain and enlargement of the right side of the neck for two weeks. He had no other symptoms or prior history of X-irradiation to the head or neck. His father, paternal aunt, and paternal grandmother had goiters. There was a 3 cm by 4 cm nodule in the right lobe of the thyroid which was slightly tender. The left lobe was palpable and questionably enlarged. The serum thyroxine was 7.7 μg/dl; sedimentation rate, 20 mm/hr; 24-hr thyroidal I-131 uptake, 4% (normal 10-30%); and the thyroid scan demonstrated diffuse decreased uptake throughout the gland. Aspirin was prescribed for subacute thyroiditis. The patient did not seek follow-up until four months later when he presented for shortness of breath that he noted while working strenuously as a farmer. He was referred to me for treatment. He had noticed progressive enlargement of the anterior neck without pain or weight loss. On physical examination, the thyroid measured 20 cm in total width with each lobe being 12 cm in height. The goiter was firm, smooth, bosselated and extended from the angle of the mandible to the sternal notch. The serum thyroxine was 8.4 μg/dl and thyroid microsomal antibodies were negative. Fine needle aspiration biopsy identified no elements of normal thyroid tissue. The majority of cells were uniform and had scant cytoplasm. The cytological findings were compatible with chronic lymphocytic thyroiditis or undifferentiated carcinoma. Computerized tomography demonstrated multiple masses within the neck and a mediastinal soft tissue density that extended down to the carina (figure 2). At surgery, a malignant teratoma of the thyroid was found but could be only partially removed. This is a rare tumor of the thyroid which occurs most often in children and has a dismal prognosis in adults — most patients die within 10 months of diagnosis.[2] This patient was not an exception; despite radiation therapy, his disease progressed with pulmonary metastasis and death within two months of surgery.

Discussion

Each of these patients was presumed to have thyroiditis (recent and relatively sudden onset of thyroid enlargement associated with low radionuclide thyroid uptake and diffuse imaging intensity), the first having painless thyroiditis and transient hyperthyroidism and the second, subacute thyroiditis. However, nodularity that persists longer than anticipated for a benign inflammatory condition (patient 1) or increases in size (patient 2) warrants further studies. Fine needle aspiration biopsy is safe, easy to perform,[1] and accurate,[3] but requires expertise in cytological interpretation. Both patients had underlying malignancy accompanying or mimicking thyroiditis. Such cases of "pseudothyroiditis" are most likely due to thyroid carcinoma but other malignancies such as parathyroid carcinoma have mistakenly been diagnosed as thyroiditis as well.[4] Other benign conditions such as hemorrhage into a cyst or into an adenoma can also be confused with thyroiditis. In such cases of "thyroiditis," fine needle aspiration thyroid biopsy leads to the correct diagnosis, excludes malignancy, and avoids prolonged delay in treatment.

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LEARNING WITHOUT WORDS

Growing Pains

Jonathan J. Berry, M.D.

• *Severe osteoarthritis may be the clue to acromegaly.*

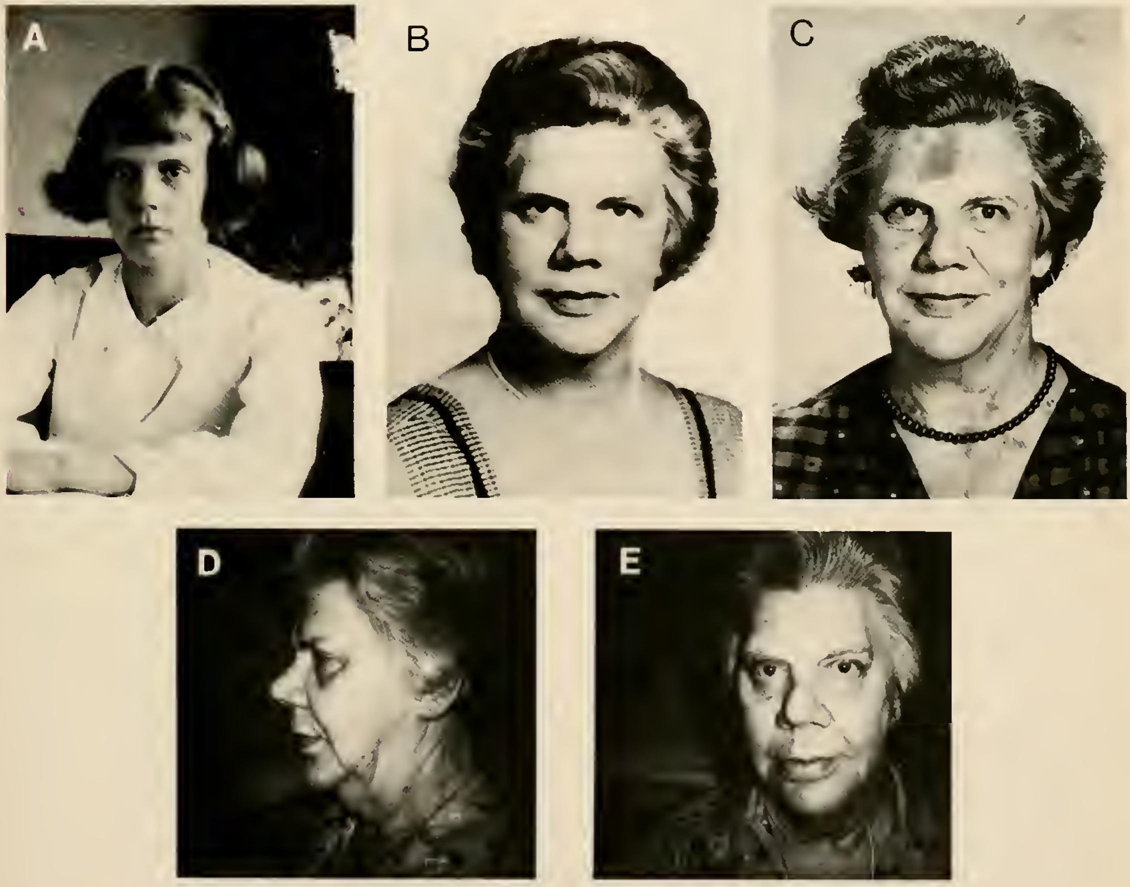

Figure 1. *Pictures of patient, D. B., at ages 12(A), 40s(B), 50s(C) and 70s(D, E) showing the development of acromegalic features over time.*

ONE of the classic problems in outpatient medicine is looking at a simple problem and not seeing the broad picture. D.B. was a case in point. Her visit was scheduled at the end of the day in my clinic and she complained of the mundane problem of sore joints. My first thought was that she was just another 73-year-old woman with degenerative joint disease and that Indocin or Motrin would solve the problem. Everything else on her physical examination was normal except that she fit into that broad category of unusual-looking adults. Just in case, however, I performed the routine laboratory tests including rheumatoid factor, sedimentation rate, electrolytes, hemogram, thyroid panel (all normal), as well as getting hand, hip and knee films. She was scheduled for orthopedic consultation. Not too long after this I received a call from an orthopedic resident telling me about the films ("osteoarthritis") and mentioning parenthetically that "Yes, she does look out of the ordinary. Her face and features are in general larger than ordinary, and has anybody thought of acromegaly?" Now, I thought, what are the chances that a 73-year-old undi-

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From Box 31187 Duke Hospital, Durham 27710.

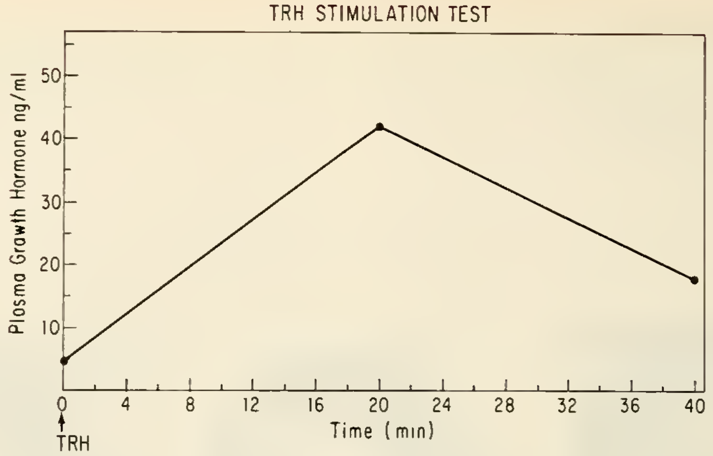

Figure 2. *At Time = 0, 500 ug TRH are administered to the patient in a supine position over 15-30 seconds. Plasma growth hormone is measured at time 0 and at 20 and 40 minutes. In normals, growth hormone secretion is not stimulated as opposed to the paradoxical response shown in this figure.*

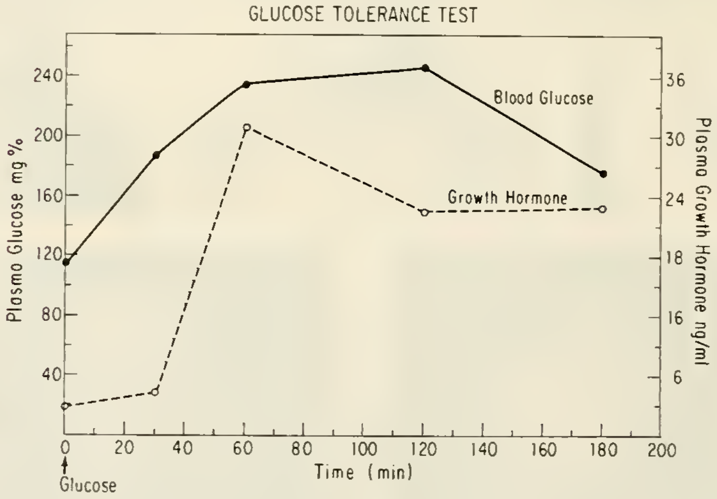

Figure 3. *At Time = 0, 100 g of glucose is given by mouth and serum glucose and growth hormone levels are measured at times 30, 60, 120 and 180 minutes. In normal patients glucose suppresses growth hormone secretion but a paradoxical response such as the one depicted in this figure is noted in acromegalic patients. Notice also the mild glucose intolerance with a two hour past prandial blood sugar of 240 mg/dl which is fairly common in acromegaly.*

agnosed acromegalic would walk into my office, given that the disease occurs approximately once per 25,000 people and between 60 and 90% of these people die by age 60, often of hypertensive and cardiovascular complications? The answer was practically nil! Most endocrinologists at Duke have seen only a handful of these patients in years of seeing a referred, sub-selected group. But my curiosity was piqued nonetheless, so on her return visit my clinical skills were more acutely sharpened for a potential diagnosis. I enlisted the service of several colleagues more experienced than myself and after gazing upon D.B. and hearing the story her diagnosis was "obvious," so I'm told. Upon closer questioning, D.B. had had arthritic symptoms for years and had been shuffled through the medical grind at various institutions with prescriptions that had included physical therapy, steroid injections and various analgesics. Her history was remarkable otherwise for some cardiac rhythm abnormalities and bilateral hearing deficits. Upon specific questioning she admitted to growing out of her high school ring as well as numerous pairs of shoes. Her

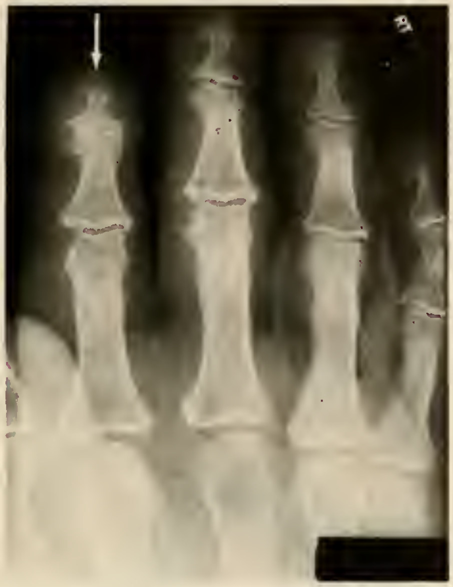

Figure 4. *The white arrow is pointing to the characteristic spade like distal tufts on this hand radiograph typical of the syndrome of acromegaly.*

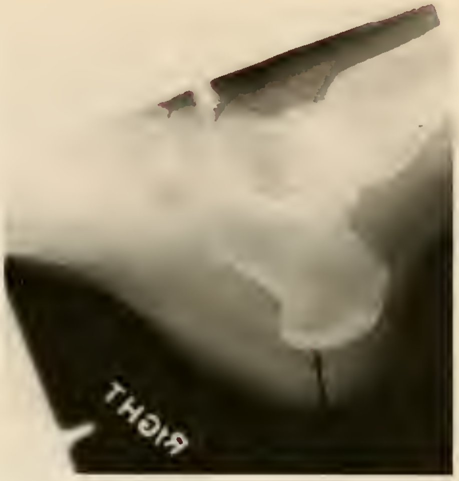

Figure 5. *Lateral foot films of the patient, D.B., with black arrow showing heel pad thickness of 26 mm in this case. The upper limit of normal for females is 21 mm.*

story, as well as her physiognomy, were certainly consistent with acromegaly (Figure 1) but now, as her physician, it was incumbent upon me to prove this hypothesis.

The workup of acromegaly, I'm sure, does not lie on the tip of every clinician's tongue. Most of us know that acromegaly is a disease of the pituitary, usually an eosinophilic adenoma of the anterior pituitary, which produces an excess of growth hormone. Growth hormone, through the intermediary action of somatomedin C stimulates various tissues to grow. The obvious diagnostic test then is to measure growth hormone levels and, in nine out of 10 cases of acromegaly, these levels are elevated (greater than 5 mg/ml) but in 10% of cases they are within normal limits. D.B.'s fasting growth hormone level was 2.9 mg/ml which is clearly within normal limits. The key point here is that, even when the fasting level of growth hormone is normal, most acromegalics will have abnormal dynamic responses to several physiologic manipulations including glucose tolerance test (figure 2) and TRH stimulation (figure 3). Figures 2 and 3 show D.B.'s growth hormone response to glucose load and to TRH stimulation. Both should suppress growth hormone in people with normally functioning pituitary glands. In D.B. there was a paradoxical rise which is characteristic of the autonomous, growth hormone-producing adenomas present in acromegaly.

Recently it has been found that serum concentrations of the effector of growth hormone, somatomedin C, are a better indicator of integrated growth hormone activity than is a single growth hormone measurement. D.B.'s somatomedin C level was 3.5 u/ml (normal for females being 1.8 u/ml). We hope to be able to follow the level of somatomedin C to monitor disease activity during treatment.

Findings related to this patient's acromegaly include spade-like distal phalangeal tufts on hand radiographs (figure 4) and thick heel pads on lateral foot films (figure 5). Her heel pads measured 26 mm; the upper limit of normal for females is less than 21 mm. She had mild glucose intolerance with a two-hour postprandial glucose level of 246 mg/dl. Glucose intolerance or even frank diabetes is fairly common in this disorder. Her ECG showed frequent premature ventricular beats and her chest x-ray revealed an enlarged heart, both of which are not unexpected in acromegaly. Interestingly, lateral skull films and computed tomogram of the head showed no sella turcica enlargement, implying that the functioning pituitary adenoma was not large. Consistent with this supposition was our finding that other pituitary hormones including luteinizing and follicle stimulating hormone and prolactin were all within normal limits for a postmenopausal woman.

Given this patient's advanced age and symptoms limited to rheumatologic problems — a common presenting complaint for acromegaly, by the way — I elected not to treat with surgical extirpation via the transphenoidal approach. Instead we used radiation therapy in conjunction with bromocriptine, a drug which lowers growth hormone in some patients with acromegaly. As an outpatient, D.B. received 5000 rads of radiation focused on the sella and fractionated over 30-day period. She takes 7.5 mg of bromocriptine a day. After she lost 30 pounds, her major problem, hip pain, was treated with bilateral hip replacement.

D.B. taught me a lot about stepping back and viewing the patient broadly rather than narrowly addressing a single problem. She is a remarkable example of how the medical system can overlook a disease that is rare yet so easily diagnosed simply by thinking of it. Once you see one acromegalic, the next one, if there is one, will not slip through your hands. She also demonstrates how knowing the physiology of a disease process allowed the diagnosis to be made — i.e., by dynamic testing rather than being satisfied with a normal resting growth hormone level.

Finally, D.B. taught me to treat the last clinic patient of the day like the first one, with an open mind.

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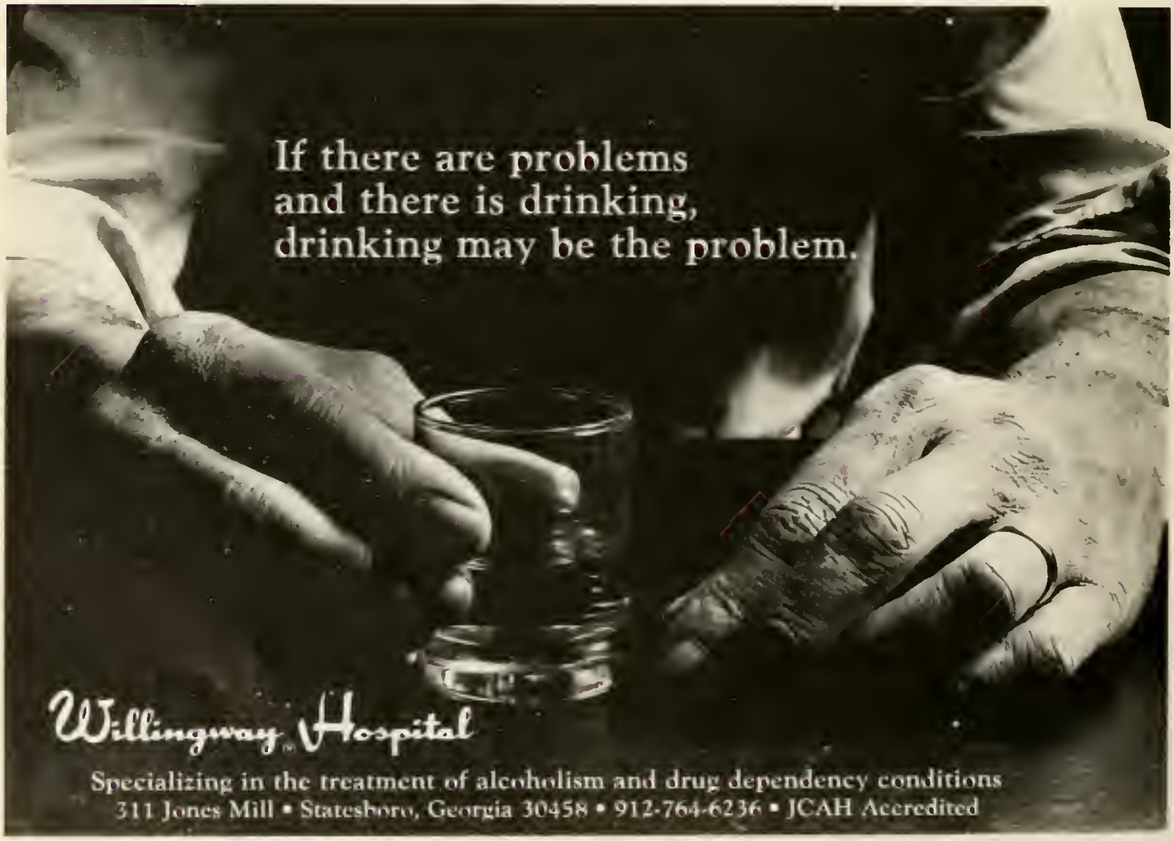

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(BRIEF SUMMARY)

DESCRIPTION
Each tablet contains 200 mg meprobamate and 325 mg aspirin.

INDICATIONS
Adjunct in short-term treatment of pain accompanied by tension and/or anxiety in patients with musculoskeletal disease. Clinical trials demonstrated that in these situations relief of pain is somewhat greater than with aspirin alone. Effectiveness in long-term use, i.e., over 4 months, has not been assessed by systematic clinical studies. Physicians should periodically reassess usefulness of drug for individual patients.

CONTRAINDICATIONS
ASPIRIN: Allergic or idiosyncratic reactions to aspirin or related compounds.

MEPROBAMATE: Acute intermittent porphyria, allergic or idiosyncratic reactions to meprobamate or related compounds, e.g., carisoprodol, mebutamate, or carbromal.

WARNINGS
ASPIRIN: Use salicylates with extreme caution in patients with peptic ulcer, asthma, coagulation abnormalities, hypoprothrombinemia, vitamin K deficiency or those on anticoagulants. In rare instances, aspirin in persons allergic to salicylates may result in life-threatening allergic episodes.

MEPROBAMATE: DRUG DEPENDENCE
Physical and psychological dependence and abuse have occurred. Chronic intoxication from prolonged ingestion of, usually, greater than recommended doses is manifested by ataxia, slurred speech, and vertigo. Therefore, carefully supervise dose and amounts prescribed and avoid prolonged use, especially in alcoholics and others with known propensity for taking excessive quantities of drugs. Sudden withdrawal after prolonged and excessive use may precipitate recurrence of preexisting symptoms, e.g., anxiety, anorexia, or insomnia, or withdrawal reactions, e.g., vomiting, ataxia, tremors, muscle twitching, confusional states, hallucinosis, and, rarely, convulsive seizures. Such seizures are more likely in persons with CNS damage or preexistent or latent convulsive disorders. Onset of withdrawal symptoms occurs usually within 12 to 48 hours after discontinuation; symptoms usually cease within next 12- to 48-hour period. When excessive dosage has continued for weeks or months, reduce dosage gradually over 1 to 2 weeks rather than stop abruptly. Alternatively, a short-acting barbiturate may be substituted, then gradually withdrawn.

POTENTIALLY HAZARDOUS TASKS: Warn patients meprobamate may impair mental or physical abilities required for potentially hazardous tasks, e.g., driving or operating machinery.

ADDITIVE EFFECTS: Since CNS-suppressant effects of meprobamate and alcohol or meprobamate and other psychotropic drugs may be additive, exercise caution with patients taking more than one of these agents simultaneously.

USAGE IN PREGNANCY AND LACTATION:
An increased risk of congenital malformations associated with minor tranquilizers (meprobamate, chlordiazepoxide, and diazepam) during first trimester of pregnancy, has been suggested in several studies. Because use of these drugs is rarely a matter of urgency, their use during this period should almost always be avoided. The possibility that a woman of childbearing potential may be pregnant at time of institution of therapy should be considered. Advise patients if they become pregnant during therapy or intend to become pregnant to communicate with their physicians about desirability of discontinuing the drug.

Meprobamate passes the placental barrier. It is present both in umbilical-cord blood at or near maternal plasma levels and in breast milk of lactating mothers at concentrations two to four times that of maternal plasma. When use of meprobamate is contemplated in breastfeeding patients, consider the drug's higher concentrations in breast milk as compared to maternal plasma levels.

USAGE IN CHILDREN: Keep preparations with aspirin out of reach of children. Equagesic® (meprobamate with aspirin) is not recommended for patients 12 years of age and under.

PRECAUTIONS
ASPIRIN: Salicylates antagonize uricosuric activity of probenecid and sulfinpyrazone. Salicylates are reported to enhance hypoglycemic effect of sulfonylurea antidiabetics.

MEPROBAMATE: Use lowest effective dose, particularly in elderly and/or debilitated, to preclude over-sedation. Meprobamate is metabolized in the liver and excreted by the kidney; to avoid excess accumulation exercise caution in its use in patients with compromised liver or kidney function. Meprobamate occasionally may precipitate seizures in epileptic patients. It should be prescribed cautiously and in small quantities to patients with suicidal tendencies.

ADVERSE REACTIONS
ASPIRIN: May cause epigastric discomfort, nausea, and vomiting. Hypersensitivity reactions, including urticaria, angioneurotic edema, purpura, asthma, and anaphylaxis may rarely occur. Patients receiving large doses of salicylates may develop tinnitus.

MEPROBAMATE: CNS: Drowsiness, ataxia, dizziness, slurred speech, headache, vertigo, weakness, paresthesias, impairment of visual accommodation, euphoria, overstimulation, paradoxical excitement, fast EEG activity.

GI: Nausea, vomiting, diarrhea.

CARDIOVASCULAR: Palpitation, tachycardia, various forms of arrhythmia, transient ECG changes, syncope, hypotensive crisis.

ALLERGIC OR IDIOSYNCRATIC: Milder reactions are characterized by itchy, urticarial, or erythematous maculopapular rash, generalized or confined to the groin. Other reactions include leukopenia, acute nonthrombocytopenic purpura, petechiae, ecchymoses, eosinophilia, peripheral edema, adenopathy, fever, fixed drug eruption with cross-reaction to carisoprodol, and cross-sensitivity between meprobamate/mebutamate and meprobamate/carbromal. Rarer, more severe hypersensitivity reactions include hyperpyrexia, chills, angioneurotic edema, bronchospasm, oliguria, and anuria. Also, anaphylaxis, exfoliative dermatitis, stomatitis, and proctitis. Stevens-Johnson syndrome and bullous dermatitis have occurred.

HEMATOLOGIC (SEE ALSO "ALLERGIC OR IDIOSYNCRATIC"): Agranulocytosis, aplastic anemia have been reported, although no causal relationship has been established, and thrombocytopenic purpura.

OTHER: Exacerbation of porphyric symptoms.

DOSAGE AND ADMINISTRATION
Usual dose is one or two tablets, 3 to 4 times daily as needed for relief of pain when tension or anxiety is present. Not recommended for patients 12 years of age and under.

OVERDOSAGE
Treatment is essentially symptomatic and supportive. Any drug remaining in the stomach should be removed. Induction of vomiting or gastric lavage may be indicated. Activated charcoal may reduce absorption of both aspirin and meprobamate. Aspirin overdosage produces usual symptoms and signs of salicylate intoxication. Observation and treatment should include management of hyperthermia, specific parenteral electrolyte therapy for ketoacidosis and dehydration, watching for evidence of hemorrhagic manifestations due to hypoprothrombinemia which, if it occurs, usually requires whole-blood transfusions. Suicidal attempts with meprobamate have resulted in drowsiness, lethargy, stupor, ataxia, coma, shock, vasomotor and respiratory collapse. Some suicidal attempts have been fatal. The following data, reported in the literature and from other sources, are not expected to correlate with each case (considering factors such as individual susceptibility and length of time from ingestion to treatment), but represent usual ranges reported. Acute simple overdose (meprobamate alone): Death has been reported with ingestion of as little as 12 grams meprobamate and survival with as much as 40 grams.

BLOOD LEVELS
0.5-2.0 mg percent represents usual blood-level range of meprobamate after therapeutic doses. The level may occasionally be as high as 3.0 mg percent.

3-10 mg percent usually corresponds to findings of mild-to-moderate symptoms of overdosage, such as stupor or light coma.

10-20 mg percent usually corresponds to deeper coma, requiring more intensive treatment. Some fatalities occur.

At levels greater than 20 mg percent, more fatalities than survivals can be expected.

Acute combined overdose (meprobamate with other psychotropic drugs or alcohol): Since effects can be additive, history of ingestion of a low dose of meprobamate plus any of these compounds (or of a relatively low blood or tissue level) cannot be used as a prognostic indicator.

In cases of excessive doses, sleep ensues rapidly and blood pressure, pulse, and respiratory rates are reduced to basal levels. Any drug remaining in stomach should be removed and symptomatic treatment given. Should respiration or blood pressure become compromised, respiratory assistance, CNS stimulants, and pressor agents should be administered cautiously as indicated. Diuresis, osmotic (mannitol) diuresis, peritoneal dialysis, and hemodialysis have been used successfully in removing both aspirin and meprobamate. Alkalinization of the urine increases excretion of salicylates. Careful monitoring of urinary output is necessary, and caution should be taken to avoid overhydration. Relapse and death after initial recovery have been attributed to incomplete gastric emptying and delayed absorption.

HOW SUPPLIED
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North Carolina Medical Journal

Features for Patients September 1984

Medical Mystery And The Whistle Blower

Mebane H. Burgwyn

Mebane Burgwyn is a remarkable lady whose "projects" have included writing books for children, serving on the Board of Trustees of the University of North Carolina, and counseling students in the public schools while helping to run Occaneechee Farms with her husband and raising four children. When her cancer was discovered almost one year ago, we asked her to begin another project: writing an account of her chemotherapy and recovery. Her story which follows is unlike anything we have published before in the North Carolina Medical Journal. *We hope you like it.*

The Editors

In retrospect, those first moments in the doctor's private office seem brief, yet endless — as if there were no beginning, only infinite stretches of time that reached down a long corridor leading to a concealed door toward which I was moving with the dream-like quality of slow motion. I saw the impact of shock on my husband's face, a paling of his sunbrowned skin, pain in the dark, slightly hooded eyes, and I was acutely conscious of concern in the doctor's grey eyes behind silver-rimmed glasses. I saw his sensitive mouth beneath the trim grey mustache speaking words he did not want to utter. Though his voice was evenly modulated I felt his reluctance to tell us what the tests had shown.

My own reaction was incredibly low-keyed, unshaken. The beautiful batik hanging in bold tones of black and rust and ivory, suspended along the far wall above the heads of these two men who were extremely important in my life, seemed the major focus of my attention. A neat display of books filled the shelves behind Dr. Francis, contrasting with the littered desk behind me, a disorder which was the undeniable evidence of a man whose professional life was filled with interruptions by insistent needs of his patients, including my own cries for help during the eighteen months he had searched for answers to my perplexing questions. He had spent countless hours studying the volumes of records from several hospitals, trying to find some thread of consistency, some clue upon which to hang the cause of recurring symptoms that had followed a long and painful collagen vascular disease suffered in April 1969.

It was clear on this October day of 1983 that further tests were necessary and that Dr. Francis wanted no time wasted. So, within a matter of slow-motion moments, I was once again, for the third time in 1983, confined within the protective walls of the huge University Hospital.

Any patient who enters a teaching hospital encounters varied levels of medical attention, depending, of course, upon the nature and intensity of his illness. Moving clockwise from perfect health around a circle toward possible or ultimate death, a patient at the 90 degree point of illness, that is, east of the starting point, has a great deal of time to think.

He is expected, just inside the front door to give details of all vital identification and insurance information. Past this barrier comes the journey to one's assigned room and, once settled, there comes the intern's chance to record the history of this case (and all preceding cases). It matters not how many times this information has been given, how detailed the records

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From Route 1, Box 424, Jackson 27845.
Illustrations by Ernest Craige, M.D.
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from all one's previous hospitalizations, an enthusiastic intern with eclectic counseling techniques can make every ache seem the very one upon which hinges the crux of this particular problem, and the unwary patient is apt to get carried away with the importance of making it all very clear. If the intern stifles a yawn, however, beware. He has, after all, been up the entire night with other patients and may appreciate a shortened version of the history.

Now, with this inquisition over, the nurses begin their visits to take blood pressure and give minor instructions. They are, for the most part, jocular and pleasant, taking care of a dozen little things to make life routine and as pleasant as possible under the circumstances. It is then that the 90 degree patient has time to don a gown unless admission was precipitous and unexpected, in which case the arms are slipped into a sterile thigh-high garment which may or may not have ties to bring it together in the back. Once tucked beneath clean abrasive sheets, there comes the opportunity to make judgment about the general state of the room: size, cleanliness, equipment, efficiency of gadgets; to decide which of the nurses will be a challenge; and to think about life in general, how many plans and appointments one should have canceled and whatever led to arrival here in the first place.

At the 180 degree level, the patient's condition is obviously more critical so things are speeded up and thinking is side-tracked, not only by physical discomfort but also by frequent visits of both interns and residents for whom this is a good opportunity to find out how well they have learned from their professors. Here is the golden gift of chance for them — an opportunity to make a discovery about this illness which may have been completely overlooked by doctor or surgeon. Therefore, precious hours, wrested from endless demands upon their time, are spent by these young students of medicine trying to find yet another clue as to the cause of this particular illness. Even if the patient had the inclination to think, there really isn't time.

At the 270 degree level of illness, the doctors and surgeons themselves come by at regular intervals, going through familiar routines that reveal to them secrets the patient can in no way hide. Even the blackest truth of one's soul is discovered, sometimes in total darkness, with the patient staring obediently at an illusive dot on the opposite wall. Blood vessels inside the dark pupil of an eye can become relentless lie-detector devices through which the doctor determines what right the patient has to occupy the bed in this room. Reflexes, absolutely beyond control when the rubber bludgeon thumps critical points of the limbs, become tattletales. Thought by the patient in this condition is erratic and sometimes irrelevant.

Three hundred and sixty degrees could be, of course, the end of the beginning or the beginning of the end. Thinking is out of the question as the patient is rolled on a sanitized stretcher immediately into Intensive Care or is pretty soon wheeled discreetly out to make room for new arrivals.

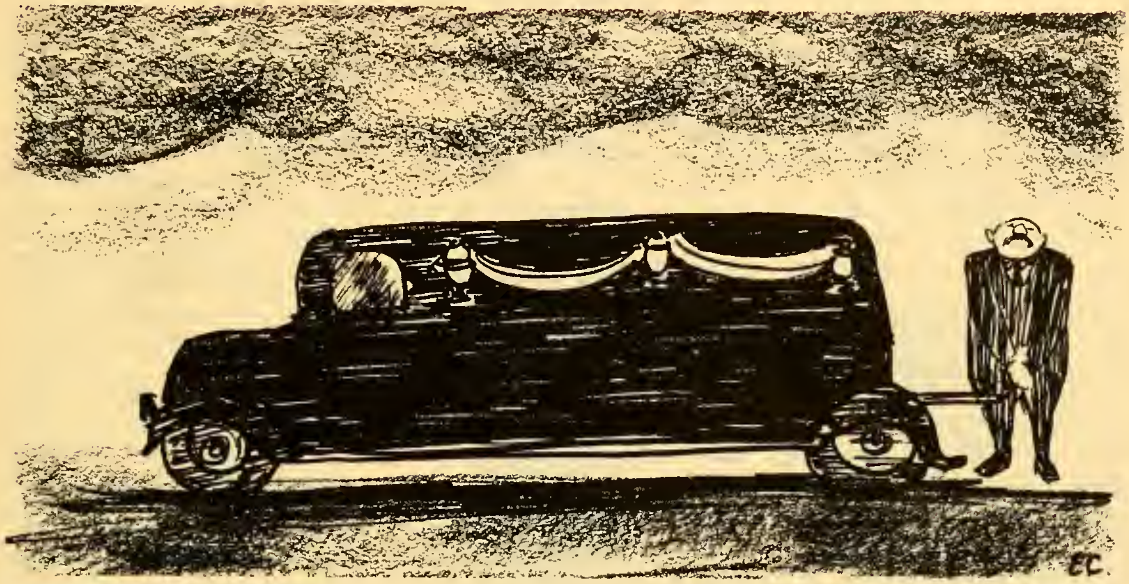
Back in April of 1969, I entered the Roanoke Rapids Hospital somewhere between the 270 and 360 degree levels and for two weeks was watched over day and night by all kinds of people who came and went — relatives, friends, doctors and their consultants and even drifters who wandered in while they were waiting to see other patients. One strange lady who came by every day said to me during one of her visits, "I told my Mama last night you had so many flowers in here it looked like you wos already laid out."

I was, indeed, laid out and I may have been at one of those points of distress that touched my strange sense of humor because the comment struck me as so funny I laughed everytime my wandering mind focused upon it.

I was laid out with alternating chills and fever — 105-106, chest pains, legs and arms and former abdominal scars covered with bruise-like spots that were extremely painful. Scarlet hemorrhages blotted out the whites of my eyes; mouth and throat were covered with painful white lesions, lips so crusted and dry that milk was the only food I could tolerate. Hallucinations removed me occasionally from all pain and caring and, upon any slight elevation of head and body, I blacked out so completely that it was impossible to get X-rays in a standing or even a sitting position. There was no arguing the fact that I was laid out.

A great deal of activity went on in order to discover the cause of this sudden physical breakdown of a patient who only one week earlier had been enjoying total health. Doctors from other hospitals were called in but with no diagnosis forthcoming and my condition apparently worsening, I was sent at the end of two weeks to Memorial Hospital in Chapel Hill. That trip was memorable to me only because I was sent in a funeral-home ambulance instead of the hospital ambulance, which happened to be in use at the time. I would not have known the difference had I not, enroute, suddenly needed to urinate. Such vehicles are not equipped with life sustaining devices for any emergencies of this type and the poor funeral director who happened to be a friend was forever humiliated because he had no facility for taking care of my particular need on this occasion. He told me much later that he always carried a bedpan after that although I was never able to imagine what earthly use it could be to the clients he usually conveyed.

After my sister-in-law, Margaret, who was riding with me found a discarded flower vase, thus providing me with a vessel that was adequate if not comfortable, I found the incident helpful for it diverted my feverish brain into an amusing train of thought. My brilliant and caustic father-in-law, that Superior Court Judge who on an occasion had be-



"I thought I told you not to get Lucius for my funeral. It seems you could have honored my simple request."

came very ill, stated quite clearly to his gentle, fun-loving wife that in the event he did not live through this illness, he wanted her at all costs to avoid having Lucius Northrup handle his funeral or transport him to his grave. When his illness grew worse and his doctor finally administered penicillin, the Judge suffered a severe reaction and went into a coma. Immediate ambulance service was imperative. Unfortunately, Mr. Northrup's vehicle was the only one available for the emergency. As they rolled the Judge outdoors on the stretcher and were sliding him into the ambulance, Judge regained consciousness momentarily and looked up to find the mortician bending over him. Though he was too ill to rise from the stretcher, he called out to his wife, "Josephine, I thought I told you not to get Lucius for my funeral. It seems you could have honored my simple request and found somebody else to do this."

With these and other thoughts teasing my illogical state of mind enroute to Memorial Hospital, I survived the trip barely conscious, remembering very little of what took place during the next several days — or weeks. My life had no relation to time.

Four more weeks of intensive tests in Chapel Hill proved equally as frustrating to the doctors there. Hesitant to administer medication when the tests presented conflicting and divergent results, the doctors were attentive but unreassuring to my husband and family and they sometimes seemed frantic. Their relief was clearly apparent when I suddenly began to improve "in spite of and not because of us," the doctor in charge of my case told me.

My recovery was extremely slow, especially my effort to walk on feet that were unbearably sore as if all tissue under the soles was bruised. The waxed floors of the hospital corridor became a pit of red hot coals. Although I was told this still undiagnosed illness included vasculitis and nerve damage, I did not know until two years later when I was referred to a rheumatologist at Duke Medical Center, that I had suffered a collagen vascular disease which still could not be diagnosed because the syndrome of symptoms was different from any that had been seen at either of the hospitals where I had been a patient.

Under this doctor's care I became stronger; yet problems continued to plague me. There was a bronchial infection which led to the partial collapse of one lung and, in the summer following that, a bladder operation. My vision was affected and I gradually lost more than fifty percent of my hearing acuity. Two years later, I suffered what was called a toxic reaction to medication given for cystitis and had a two-week stay at Duke Hospital while they searched for reasons that were not forthcoming. The next year, Dr. Williams removed a defunct gall bladder and sometime later there was what appeared to be a recurrence of the collagen disease with all the painful symptoms reappearing, though in a milder form.

Within a year I was back at Duke with severe abdominal pain and a high amylase count which might indicate problems of the pancreas. I was convinced that I was coming apart, piece by piece, like the 1959 Plymouth convertible we once allowed our sixteen-year-old son to have and which my husband swears he replaced, part by part, except for the steering wheel.

Twice during this year of 1983 I had been in the hospital for CAT scans because of abdominal pain and twice had been dismissed, leaving both Dr. Francis and his patient less than satisfied with test results. Then, what was I doing here, my aching body once more tucked in a white sterile bed, my spirit fettered like broken wings? The answer to this was Dr. Francis. He was not a doctor who gave up easily; nor was he one who dismissed pain as a figment of the imagination.

He ordered another ultrasound test and the large mass was found, confirmed later by another CAT scan. A biopsy followed, indicating malignant cells, and then came surgery to remove a section of the mass in order to determine the type of cells that must be treated. With the diagnosis finally completed, Dr. Francis and Dr. Gordon, the hematologist he had called in to take over my case, came in and sat down to discuss my situation — to give me answers that came almost as a relief.

The mass, a lymphoma located in the abdominal cavity, had been missed in both previous CAT scans, one being too high, one too low. How long it had been there growing silently, insidiously, was impossible to say. How much it had contributed to other difficulties was imponderable. Whether it was a cause or a result or had anything to do with the collagen vascular illness was a matter of conjecture, but there it was — a problem that was definite and treatable.

I was not promised a hundred percent chance of recovery, neither was I given any promise of a rose garden for the months ahead. But I was given a choice — six months of treatment with the outlook on the plus side of bright for this type of cancer, or —

Well, there was no choice. My husband always spoke of my varied interests as "projects" and was both amused and tolerant of my efforts whether it might be writing, art lessons, guitar lessons, teaching, cross-stitching, or working with various state and local boards. Now, I had been given the ultimate project. The odds were in my favor, whatever the cost in side effects. Had the coin come up on the flip side, my thinking would undoubtedly have taken different directions. I would have had to gear myself to making each day count. I would have had to dig deep for ways to cope. As things were, I was being promised uncomfortable side effects, loss of hair, six months of some kind of hell. But the chance of recovery beckoned me like a bright and shiny star. Chemotherapy. What a golden word of hope that seemed to be. Perhaps my thin straight hair might even grow back lustrous and curly. It seemed a dream worth dreaming.

My initial visit to the Oncology Clinic while I was still recovering from surgery gave me a shock. From my wheelchair I looked out over the large reception room. There were thirty-seven chairs and all of them were occupied, most of them by patients waiting to be seen, some of whom were so obviously ill that it seemed I might be the most fortunate among them.

In the womens' bathroom a pretty, stylishly dressed lady apologized because she was crying.

"Please don't apologize," I said. "I understand. I have reason to cry, too."

"I guess everyone here does," she said, wiping her eyes.

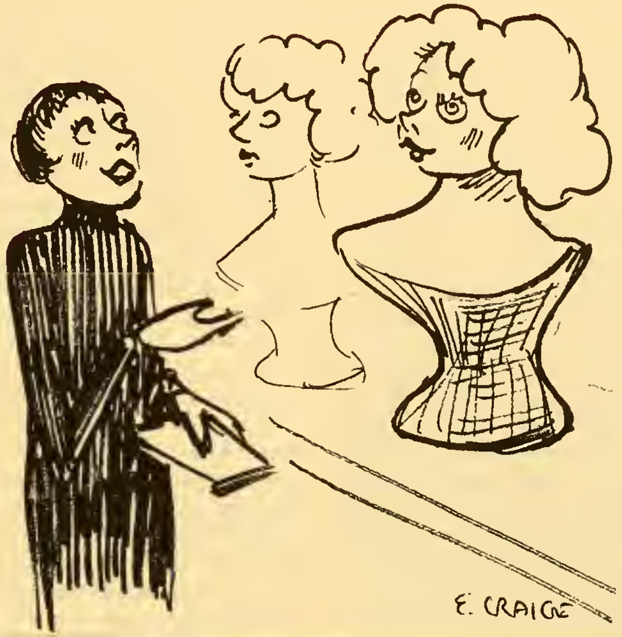
It occurred to me as I left her, still teary, that I had not cried. Not once had I cried. Maybe I was stronge, not to have cried.

At the admission desk, I was given a sheaf of records and instructions stapled together and was told to take them to the lab technicians. In the lab, someone took the papers and told me to wait outside until I was called back for blood work. From that moment I learned very quickly that waiting would be an important part of the treatment.

Seated in the reception room, I looked about me at pale faces; at the missing ear and the bald heads of men who wore no wigs to cover their bare white skin; at the young girl, just budding into womanhood, who wore a bandana kerchief to hide the brand that marked her as one of us. It was then that the waiting became tolerable. I knew that I was waiting because the doctors were addressing their attention to the urgent needs of these people as their names were called and that I would receive the same unstinting care and interest when my time came for consultation.

You waited to be called back into the lab where blood was drawn and checked carefully by the doctor before he saw you. Then you reported immediately to the nurses' station for a recording of weight and temperature after which there was another wait until your doctor was ready to see you. This could be fifteen minutes or two hours. Once in his examining room, however, the amount of time he spent with you was governed by your individual need. There was never a sense of haste or pressure of time. His examination was thorough with caring attention to every comment or complaint or question written down during the week at home. If there was a problem related to a specific field of medicine, a specialist in that area was called in as a consultant.

After this examination, the doctor then sat down again and gave a full evaluation of your condition with a discussion of your treatment for this day and the week until your return visit. You knew what you might expect and that you could call for help anytime during the twenty-four hours of any day. Usually, I left Dr. Gordon's office with an upbeat reaction, encouraged and reinforced with determination to get through this treatment and the seven days until my return.



"With a little more out in front, you might be Dolly Parton."

Back in the reception room after the doctor's examination, you waited for your turn in the chemotherapy lab. There were three technicians who administered treatment to patients in three reclining chairs and to those who might be occupying the three beds in an adjoining room. There was also a space at the desk just inside the door for those patients requiring only brief treatment.

That first day Elizabeth, a petite, brown-eyed blonde with brisk and bouncy good humor, gave me pamphlets related to cancer in general and lymphoma in particular. She then covered me with a warm blanket and handed me a candy lozenge to suck while she sat by my reclining chair and administered the continuous flow of saline solution and the chemicals that I would be getting once a week for two weeks. I understood that following these two weeks, I would be given a different combination of drugs twice, once each week. Then this four-week cycle would be repeated and the entire series would be given in six cycles, all tailored by Dr. Gordon, for my particular needs. Twenty-four weeks. Six months. It seemed an eternity.

With the medicines flowing into my veins, I soon realized that the candy was designed to cover up the strange and unpleasant metallic taste that pervaded my body.

"This vial contains Decadron and it will make you feel a prickling sensation in the vaginal area for just a minute. It's given to prevent nausea that the chemotherapy may cause," Elizabeth told me as she pressed the plunger of the syringe. "And this one," she said, picking up a larger syringe filled with red fluid, "is Adriamycin, the first of the three anticancer drugs you'll get today and next week. This will make your urine turn red and it's the one that makes your hair come out."

"And when can I expect that to happen?" I asked her.

"By the third week you can expect it to fall out by the handful so stop by the K-Mart on your way home and buy yourself one of their wigs. They're inexpensive and very attractive. Don't move," she cautioned as I shifted my position. "If this fluid gets on your flesh, it will burn you."

"But you're putting it into my veins."

"I know. That's just where we want it."

"What is this stuff, anyway. Where does it come from?"

"It comes from soil fungi and is supposed to block cancer cell growth."

I watched her monitor the saline solution which was being given simultaneously and then saw her replace the first vial with another smaller vial of Vincristine, a drug derived from the periwinkle plant. It, too, she told me, interfered with abnormal cell division as did the third chemical, Cytoxin. These three drugs in combination, I learned, seemed to be more effective than any one of them alone would be. It was true that along with destroying cancer cells they also destroyed white blood cells that are so vital in fighting infection. This was the reason for making a two-week change in treatment and switching to two different drugs — Bleomycin, given by injection, in combination with Prednisone, taken orally each day at home for fourteen days. These two drugs also destroyed cancer cells but would not attack certain white cells, thereby giving the body a chance to build up a replacement of these cells.

Upon release from the hospital after my second treatment, I was happy when one of our three sons arranged to make as easy as possible a quick foray into the K-Mart on our way home. He helped me to find and assess the display of wigs and then stood off at a distance to judge each of them as I tried them on. I stood on shaky legs in front of a tiny clouded mirror seeing myself become persons

I did not know and, suddenly, I felt that this was a remarkable moment in my life, a moment of priceless fun shared with my son, a fleeting moment snatched from pain and illness to be enjoyed and remembered.

"That's it. That's the one," I heard Henry say. "With a little more out in front, you might be Dolly Parton."

The wig was short, curly and slightly blonder than my own hair. Although there could be no illusion about my resemblance to the beauteous Dolly, I was satisfied that my appearance in this wig would not be a completely shocking departure from my natural hair. So the purchase was made and I collapsed amid pillows when we were once more enroute home with the comforting thought that my approaching baldness could be camouflaged by an abundance of blonde curls.

Before the third week and the loss of hair, however, I found myself being transported back to Duke Hospital by the local Rescue Squad. For five days I remained there while Dr. Gordon had me treated for nausea and fainting and took precautions to protect me from infection as my white blood count had dropped dangerously low.

Back at home following my third treatment, this time with Bleomycin, I dutifully swallowed the Prednisone pills each night and morning and soon realized that the side effects of this combination were going to be even less pleasant than the first treatments had been. Chills and fever, which I was told might be avoided if I took Benadryl and Tylenol, occurred anyway and when I tried to walk or to feed myself, the palsy-like loss of muscular control was disconcerting. Equally as hard to bear was the pain that shot through glands in my neck behind and up towards my ears whenever I ate or drank anything, even water. It was as if I had a smashing case of mumps.

"Cut the dosage of Prednisone in half. Just take one pill a day instead of two," Dr. Gordon told me when I called him on the telephone before my return to the hospital for a fourth treatment. He also discontinued three of the four Elavil pills he had prescribed to stabilize mood changes he thought I might experience in having chemotherapy. Even this did not completely stop the shaking or the drop in blood pressure and the fainting spells when I attempted to stand or walk. Once in the night I fell in the bathroom and bruised the side of my face so that I became fearful of trying to walk alone.

I was well into the second month of treatment when I awoke one night feeling strangely numb and debilitated. My left side felt paralyzed. I sat up in a state of panic and turned on my light. My heart was barely beating against my chest; the pulse was very slow and irregular. I tried to stand and fell, weak and faint, back onto my bed. I looked at the clock. Four a.m. The witching hour. The time when many babies were born, when old people died, when others took a turn for the worse. Was I dying? I certainly felt that I was. I could not just lie here and die. There were still a lot of things I had to do. I tried again to stand. Impossible. I struggled to sit up and then reached for the blood pressure kit with which I had been keeping a record for the doctors. With the cuff adjusted, I pumped the bulb. 58/52. How low could blood pressure go before you died? Who could I ask? My husband was asleep in the next room, but he would have no idea about this. I looked at the telephone. Dr. Gordon had said I could reach him twenty-four hours a day. I needed to know. My hand closed over the receiver and I dialed the number.

A strange young voice answered when I gave my name and identified myself as Dr. Gordon's patient. "This is Dr. Andrews speaking. Can I help you?"

"I just want to know if I am dying," I said.

"Tell me. What's your problem?"

"My whole left side is numb. My heart is hardly beating. I can't stand. I faint. My pulse is weak and my blood pressure is 58 over 52."

"Well, tell me who took your blood pressure."

"I took it," I said.

"Well, Ma'am, if you can take your blood pressure, you're not dying."

I was silent for a moment, pondering the logic of this. "That's all I want to know," I said. I laid the receiver back into its cradle.

There was no real physical comfort to be found anywhere, however. Another side effect had entered my life making my days almost unbearable and my nights of restlessness no periods for relief. I began to hear music performed for me twenty-four hours a day by a splendid choral group located within my head. The mixed voices were clear and in perfect pitch as they sang songs from out of my past — songs I did not even remember that I knew: Baptist hymns, Episcopal chants, patriotic songs, "Anchors Aweigh"; popular songs, "You Needed Me"; folk songs, "I've Been Working On The Railroad"; country and western songs, "You're Always On My Mind." The maddening thing about the music was that, once started, each melody was sung through and repeated endlessly, relentlessly, never ceasing, never changing until I, driven to distraction, concentrated upon a mental switch to some other tune. Even then, the melody often slipped back into the tune I sought to escape.

Other developments were taking place. True to schedule, my hair was coming out and the process was not entirely painless. My head was distressingly sore to touch, and profuse sweating left my pillow soaked. Each morning I awoke to find mounds of hair on my wet pillow and pulled wisps of it from my mouth, saw white skin of my bare head begin to appear beneath the fine gauzy residue that defied the chemicals and remained as token salve to wounded pride. I cut this fuzz short and covered it with the wig.

"I declare, you look better than I've ever seen you look," a guest would say. Though this gave me a degree of pleasure, it was tempered with doubt.

"Nobody would ever believe you've been sick," another would comment. Absolutely no credit for all those side effects.

"You look wonderful!" Amazement in the tone.

Although my mirror revealed a darkening of skin color and a moon-face caused by Prednisone, I was aware that my friends' reaction was born of kindness. Nevertheless, I began to think I would wear the wig forever. It certainly meant instant improvement without effort. But then, one Sunday morning, a glance in my mirror brought dismay. All the curls across the whole front of my wig were shriveled and parched as if scorched. Total disaster! But I had been around no fire. What could have happened? From the kitchen came the aroma of roast beef cooking in the oven. Of course. It was steam from the pot when I had lifted the lid to check the roast. Steam had melted the ersatz hair. Back to the K-Mart. Pick up another Misty 22 in Honey Blonde.

In the meantime, a fine rash resembling German measles appeared on my body from armpits to groin, an itchy, stinging red rash. During my next visit to the clinic, Dr. Gordon called in a dermatologist so that they might come to some conclusion about which of the medicines was responsible. The wealth of side effects I was presenting was causing some consternation. They decided that I should be taken off the remaining Elavil pill and mentioned the fact that the Prednisone which I would be getting again would effect healing of the rash.

"Oh, Goody," I said, somewhat wryly. "I can rejoice. I'll be walking around with Parkinson's Disease but, never mind, my rash will be fading away." The doctors laughed.

Not so funny, however, was still another real problem. The ulcer-like sores in my mouth which made eating sheer agony began to extend down my throat and talking became difficult. I was hoarse without having a cold. The persistent congestion in the back of my throat and the constriction of my vocal chords, to say nothing of having to listen to my high-pitched voice when I talked, gave me some concern. Dr. Gordon arranged an appointment with Dr. Carroll, an ear, nose and throat specialist, but there was to be a wait of two weeks before he could see me.

Total disaster!

It was during this interval that I woke to find that the choral group had departed. I no longer heard their music and the relief was immeasurable. Then, too, Dr. Gordon had adjusted the dosage of chemicals so that I was beginning to tolerate the treatments with less severe chills and fever or nausea which always had followed one or the other of the injections. The shaking was subsiding and, finally, the diagnosis by Dr. Carroll was reassuring. The throat problem was not cancer. It was only that my vocal chords were paralyzed. Panic. Perhaps the medication was responsible? Would the condition improve when it was stopped? We'd just have to wait for the answer to that.

Best of all developments, however, was the report from the CAT scan that was done at the midpoint of my treatments.

"The mass is gone," Dr. Gordon told my husband and me after he had looked at the X-rays.

"What do you mean by 'gone'?" I asked. "You mean completely gone?"

"Yes, there is no longer any sign of the mass."

I was incredulous. I looked at him, this handsome, direct doctor whose brown eyes warmed so easily into a smile. "Would you have been worried, would I have been in trouble if it had still been there or only a little smaller? It's been only three months."

Dr. Gordon, always honest and explicit, replied. "If it had not been reduced in size at all, I would have been worried. If it had been one half smaller, I would have been concerned. If it had been considerably smaller, I would have been satisfied. But with this result I was very pleased. It puts you in the category of those who are most likely to have a complete recovery. But we will continue the cycles of treatment as they have been planned."

My husband and I agreed with the wisdom of this and I had a dream that my days henceforth would be more comfortable. But I was far from home free. Side effects still lurked, hidden and ready to strike in unexpected ways: side effects from antibiotic medication used to combat urinary infection, return of chills and fever and even the music, though it was more subdued in clarity than before and not as all-pervasive. There were long nights of sleeplessness, some of them with no sleep at all, and there were the ever-present mouth sores and fever blisters. There was the unpleasant metallic smell and taste that followed the treatments, and a distaste for food as well as the burning of my digestive system when I did eat anything. My body felt buffeted and electric with protest as the chemicals continued to course through my veins. I visualized the battle going on inside my body with cancer cells screaming in fury as they were attacked by the anti-cancer drugs. I became the cheerleader for those chemical warriors that were fighting in my behalf. My prayers were for their victory and for courage and endurance to contain the conflict and to get through each week, each day, each hour.

I read and looked at television. I cooked exotic food which had no appeal for me, and welcomed visits of family and friends who came bearing gifts of love and good wishes. Occasionally, I went out for a meal with my supportive husband who had eased the pressures of my life in so many ways but, generally, during those winter months, I welcomed the warm haven of our fireside and the view from our bay window, watching cardinals, chickadees, evening grosbeaks, finches and other beautiful birds that came to our feeder and bathed in the heated birdbath. And there were always special times when our concerned sons and cherished daughter came to help or to visit, bringing with them their lively families, filling the house with fresh young viewpoints, laughter and teasing. Through all of it, I felt the power and wonder of God's love. I was grateful for His gifts that made healing possible, for the skill and patience of Dr. Gordon who knew how to use the gifts and for Dr. Francis who was so persistent, in the first place, in his search for answers to my problems. I was touched by the prayers of my family and my friends who each week took turns transporting me the hundred miles to Duke Hospital and returning me home, often prostrate on the back seat of the car.

It was near the end of my treatments, during the last cycle, that I talked with resignation to Dr. Gordon. "It is finally clear to me," I said, "that this is going to be tough every inch of the way and I am going to be screaming and complaining right down to the wire."

"Well, good," he said, smiling at me. "I certainly wouldn't want you to change."

So huffing and puffing, I came to the day of my last visit with him and it was then that I finally experienced the only side effect listed that I had not yet felt. I had heard that word and read about it in the book that Elizabeth had given me that first day and had wondered a hundred times why it was so long coming. Dr. Gordon himself had promised that, among other side effects, I would get this feeling from Prednisone, but it had eluded me.

Now, sitting in his examination room while he checked glands, muscular reactions, heart and lungs, my body felt curiously loved and then elevated by levity to a glorious feeling that I had been promised. In spite of residual discomfort, my spirit was floating above and beyond all the agony my body had endured. I could recall the really tough days, remember the fainting, the nausea, the chills and fever, the mouth lesions and vocal problems, the shaking, the music, the glandular pain, the rashes, the debilitating weakness and general misery and know that the "project" was now behind me. I was aware that I had never been given any guarantees, but in this moment I could see these past six months as interesting, educational, rich with humor and new understanding of the trauma and pain that thousands of people face everyday. I could identify with them and appreciate the need for research to combat this terrible disease that is so prevalent in our society.

But for one long moment my mind raced far beyond these thoughts and carried my soul to intrinsic heights of triumph. I could only rejoice in having come through the six months of hell that had been necessary for any hope of recovery.

I looked at this doctor who had never once wavered in his concern for my problems or for me.

"You know, Dr. Gordon, I feel like a battered, overloaded freighter, one that has just been maneuvered through a storm over dangerous shoals by a very skilled captain."

He smiled just a little. "That's nice," he said. "It's almost poetic." And then he laughed.

And I laughed, too, succumbing to the sheer pleasure of the last side effect — euphoria and a sense of well being.

. . . succumbing to the sheer pleasure of the last side effect.

A Specialized Unit for Patients With Diabetes Mellitus

Ellen D. Davis, R.N., M.S.

What can a person expect when hospitalized for regulation and control of diabetes mellitus? Hospitalization for any reason can pose great problems for the patient with diabetes and even when the explicit purpose is to "improve control" those hazards are not eliminated. Among the potential problems are meals that are institutionally timed rather than conforming to the patient's usual routine, and meal trays that do not appear or must be delayed because of tests. Additional problems include lack of opportunity or facilities for exercise; erratic swings in blood sugar concentration resulting from the stress of hospitalization; and the upset of normal routines of self-care by health care providers. *Diabetes Forecast* (the excellent patient-centered publication of the American Diabetes Association), which has called attention to these problems for several years, urges that patients persist in their efforts to care for themselves and to assist the staff whenever they are hospitalized. Whenever that hospitalization is primarily for control of diabetes itself or for treatment of a diabetes-related illness, admission to a specialized diabetes treatment unit can minimize the problems alluded to above. One such specialized unit is located on Hanes Ward at Duke University Medical Center in Durham. Since many patients are not familiar with such specialized units, I propose to outline the workings of the Duke Unit to acquaint patients with what they may expect from hospitalization on a diabetes unit.

In general, patients gain admission to the unit on referral from their personal physician to a member of the Division of Endocrinology in the Department of Medicine at Duke, although some patients initiate the referral themselves. The length of hospital stay for diabetes control and education is usually five to ten days. As a rule, the costs of hospitalization are reimbursed by hospitalization insurance at the same level as other diagnoses and treatments. After discharge, most patients return to the care of their personal physicians, but they may continue to see the Duke consultant on a periodic basis as indicated. A discharge summary describing the course of hospital care and the recommended treatment plan is always sent to the referring physician.

Staff of the Diabetes Unit

A patient admitted to the Diabetes Unit will encounter a high level of professional competence and an appreciation of the complex medical and psychosocial aspects of diabetes. The attending physician will be an endocrinologist, a specialist in diabetes and disorders of other glandular organs (including the pituitary, thyroid, parathyroid and adrenal glands and gonads). The attending physician is assisted by a resident, a physician in training who is spending a period of time specializing in endocrinology. Since diet therapy is the keystone of diabetes treatment, each patient is seen by the dietary staff which is headed by a diabetes dietitian-clinician. The nursing staff on the Diabetes Unit have all chosen to work with this patient population and are expert in diabetes care and diabetes patient education. In addition to a head nurse, assistant head nurse and staff nurses, the Unit has a diabetes nurse clinician who has special expertise in patient education; these nurses work together continually to increase their knowledge and skills regarding diabetes. All personnel on the Diabetes Unit recognize that the care of the person with diabetes is a team effort with the patient as the most important member.

Getting a newly diagnosed patient off to a good start

Patients with newly diagnosed diabetes mellitus are admitted to the Unit in order to start them on the road to efficient self-care. Since we believe that the chronic complications of diabetes come from having an abnormally elevated blood sugar over a period of time, we are eager to arrange the best individualized medical plan to achieve tight control of blood sugar. In conjunction with the patient, the dietary staff will derive an appropriate meal plan to reach or maintain ideal body weight. If insulin or other drug therapy is indicated, the medical staff will help work out the details of treatment. The patient is given intensive individual instruction in the principles of diabetes care. Finally, because even the best of plans can have no benefit unless the patients can put them into action in their everyday life setting, the dietary and nursing staffs encourage the patients in self-management.

Helping patients who have had diabetes for many years

Many patients admitted to the Unit have had diabetes for some time. Most have not practiced the primary cornerstone of diabetes management, the individualized diabetic meal plan. Their self-care knowledge and skill need serious tune-up. They may have some of the chronic complications of prolonged high blood sugar and erratic control.

Some patients arrive feeling very ill while others feel relatively well but know that their present level of control will lead to future trouble. The key to leading a long, full life with diabetes is to keep blood sugar levels in the same range as people without diabetes. This may seem an impossibility to persons who have had erratic blood sugar levels for many years but it is an achievable goal. It does require hard work on the part of both the staff and the patients. Patients must be willing to replace old attitudes, information and behaviors with a commitment to a consistent

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From Box 3714, Duke University Medical Center, Durham 27710.

daily regimen. Patients need always to remember that the slowly developing chronic complications result from elevated blood sugar and erratic control. It is not true that complications are inevitable; in fact, complications already started can be helped by normalizing blood sugar concentrations and maintaining tight control.

Admission to the Unit

After an intensive assessment by the medical, nursing and dietary staffs, the work begins for our patients. They are encouraged to bring casual street clothes since we do not view most of them as sick but as patients in need of reorganization. The educational process begins upon admission. Whether the patients are physicians or farmers, they are in need of updating on the process of self-care in their unique life settings.

The diabetes nurse clinician or another member of the nursing staff will explain the goal and benefits of normalized blood sugar concentrations and the necessary ongoing patient involvement in gaining control of blood sugar and maintaining that control in the "real world." Explanations are given gently many times over to those feeling stressed by being in a hospital. Medical staff review the progress toward the goal of better blood sugar control and help the patient to become adept at initiating the changes needed to reach that goal. Reading materials relating to the nature of diabetes and the principles of diabetes management are provided for patients to study.

Patient involvement in education and regimen planning

We tell patients that they need two things to live fully with diabetes: the right medical plan and the wherewithal to put that plan into action, *themselves*, in their day-to-day life. We teach patients when and how to test and record urine sugar concentrations. Often we teach them how to test their own blood sugar concentration by taking a single drop of blood with a finger prick. Urine and finger prick blood sugar concentrations are tested four or more times a day in the hospital. Patients and staff study these test results to determine the most appropriate medical plan. Patients are involved in understanding this medical process and the treatment choices as well as in learning the performance skills they will need at home. We do not arrive at a medical plan "in secret" and then keep patients another week to teach them how to maintain it. Patients and staff work together to arrive at the goals simultaneously.

Patients who will be monitoring blood sugar at home will need to purchase appropriate equipment. The diabetes nurse clinician keeps abreast of the many advances and refinements in this field and can help patients choose among the alternatives available to them. The dietitian works with patients and their families to determine a meal plan for each individual. We have recently added a teaching kitchen adjacent to the Unit and plan to provide hands-on practice in meal preparation for our patients.

The goals of patient education

Our focus in patient education is always to integrate the regimen into the patient's home life. Creative problem solving about home matters is always encouraged. Typical questions are the following: How can I test my urine or blood before lunch while at work? How can I manage an evening out when the meal is going to be late? How can I accommodate extra (or less) exercise on the weekend than on weekdays? Each of these questions has as many appropriately sound medical responses as there are people asking them. With a solid background in the nature of diabetes, the aims of control, and practical knowledge and skills, patients learn to answer the questions with decreasing assistance from the professional personnel. At home they must handle the recurrent and unforeseen challenges to positive adherence by themselves.

Adjustments of insulin dosage

If patients need daily insulin, their requirements and responses are examined in detail. Finger prick blood sugar readings give invaluable information about how different types and brands of insulin or combinations of insulin work in individual patients at a particular phase of their diabetes. Each day's readings provide a look at patients' previous day's responses to constant dietary intake and the insulin plan in effect. The next day's insulin regimen can then be altered if necessary. All patients learn how to adjust their own insulin plan (that is, they learn an "algorithm") in order to maintain control at home. The only way that tight control can be maintained is for the patient to be knowledgeably in control. Fortunately, insulin changes are not needed often once patients have attained good control in the hospital, adhere to the meal plan, and know how to solve problems creatively.

Patients learn to draw up and administer their own insulin. If they have been carrying out this and other tasks correctly at home, the review and approval of the staff further increase their confidence. They also learn the newest information about insulin absorption and the most appropriate sites for insulin injection. A few patients may benefit from continuous subcutaneous insulin infusion (insulin pump), although the precise indications for this device are not yet clearly defined. In any case, if necessary, patients are outfitted with a pump and instructed in its operation.

Exercise and stress management

Exercise is an essential component of diabetes care. Street clothes and guidance from the staff enable patients to pursue consistent exercise patterns while on the Unit. The physical therapy department as well as formal, supervised exercise and training programs are available and are incorporated as needed. The ability to carry out actual exercise while on the Unit provides an opportunity for instruction in the prevention, symptoms and treatment of hypoglycemia (low blood sugar) as well as establishing a healthy pattern of behavior.

Stress can have bad effects on blood sugar control. Personnel on the Unit are aware of the importance of appropriate emotional and psychological responses for persons with diabetes. When excessive or uncontrolled stress limits the adaptation to or control of diabetes, we recommend and implement the use of relaxation techniques, biofeedback training, medications or psychiatric consultation as indicated. Of course, since the Unit is a fully integrated part of the hospital, consultations with physician specialists in ophthalmology, cardiology, orthopedics, urology and all other specialties are available and are arranged as needed. Our goal is well-informed, educated patients, adapted to the burdens imposed by diabetes and capable of caring for themselves with a little help from their friends.

Urticaria

Russell W. Eyre, M.D., Claude S. Burton, M.D., and J. Lamar Callaway, M.D.

"Doctor, I have hives." Fortunately most people can easily diagnose this rash because it frequently has disappeared when they see the doctor. Hives, welts, and wheals are all common names for these itchy, raised plaques with lighter centers and surrounding red patches. The medical term, urticaria, comes from the latin word for the stinging nettle plants, urtica. Contact with this plant produces localized hives.

One out of five people will have an episode of hives sometime during their life. Most attacks are gone in a few days or weeks but an unlucky few continue to have attacks for decades. Half of those patients with chronic urticaria, hives that last longer than two months, will continue to have hives five years later.

"Doctor, what causes these hives?" Fluid escaping from dilated leaky blood vessels causes the skin to swell. Cells called mast cells release several chemicals that cause the blood vessels to leak. These chemicals are quickly inactivated so an individual spot generally is gone in several hours. Anything under the sun, including the sun, may cause these mast cells to release their chemicals. Besides the release of chemicals from mast cells anything that causes blood vessels to dilate may make hives worse. Blushing and flushing from emotional excitement, alcohol, coffee, exercise, fever or warm baths may worsen urticaria.

Acute urticaria is often caused by foods such as shell fish, nuts, berries, eggs, cheese, chocolate or milk. These causes are usually easily recognized by the patient and avoided. Rarely the sensitivity is so great that a minute amount is enough to trigger an attack. One lady broke out after kissing her husband who had recently eaten shrimp.

Drugs, especially penicillin and aspirin, are common causes of urticaria. Dairy products may contain small amounts of penicillin that may perpetuate an eruption of hives. Aspirin increases mast cell sensitivity. In one study forty percent of all patients with urticaria improved when they avoided aspirin even though they weren't specifically allergic to aspirin.

Infections with bacteria, fungi, viruses or parasites, although frequent afflictions of man, probably aren't common causes of urticaria. In one study only four out of seventy-eight patients with an infection and hives were free from hives after their infection was treated.

Heat, cold, sunlight, water, pressure, and vibrations may all cause hives in some patients. These physical urticarias are easily tested by applying the suspected agent.

Since most cases of hives clear within two months, a detailed search for an underlying cause is unnecessary unless the hives are chronic. Unfortunately, despite the most expensive and detailed examinations modern medicine can offer, a cause of hives will be found in only one out of four patients with chronic urticaria. Most of those causes are evident after a careful history and physical examination. Laboratory tests are seldom helpful unless the history or physical uncovers another reason for performing them besides hives.

"Doctor, what can I do for these hives?" It's obvious that if a cause such as a food allergy can be identified that food should then be eliminated. Occasionally a strict diet will result in improvement indicating an unsuspected food allergy. All the patient's medications should be examined including vitamins, laxatives, antacids and other nonprescription drugs. Therapeutic trials of antibiotics may rarely reveal a hidden infection. Eliminate anything that leads to blushing or flushing.

Several drugs are available to counter the effects of histamine, one of the chemicals released from mast cells. There are several different chemical classes of antihistamines and an individual patient may respond to only one class. We generally prefer to start with hydroxyzine but quickly change to another class of antihistamines or add another drug if no response is noticed after an adequate trial. A new drug used for stomach ulcers, cimetadine, also counters some effects of histamine and can be a useful addition to traditional antihistamine therapy.

Other drugs, commonly used to treat asthma, such as terbutaline, ephedrine, and theophylline may help to stabilize the release of chemicals from mast cells. Systemic steroids such as prednisone often clear hives but using prednisone for long periods is not justified in uncomplicated hives because of the side effects of prednisone.

The most important therapy of urticaria is reassurance that this disturbing rash is only rarely associated with a serious underlying disease and usually only lasts a few weeks.

From the Department of Medicine, Duke University Medical Center, Durham 27710.

EDITORIAL

Training Is No Substitute For Education

Eugene A. Stead, Jr., M.D.

THE current interest in North Carolina to prepare its young people for the work force by vocational schooling makes a review of the differences between education and training timely.

The words *education* and *training* are frequently used interchangeably. We need to appreciate the differences and similarities between these two modalities and not confuse one with the other.

In a narrow sense, education and training have the same goals. Each attempts to establish new learning patterns in the central nervous system which facilitate the performance of new tasks and improve the performance of previously learned tasks. An educational program attempts to produce a wide range of changes in the nervous system and to increase the general capacity of the neural network to store information and to move and rearrange facts. We use the word *memory* to describe the acquisition and storage of information and the word *thinking* to describe the movement and rearrangement of countless bits of information.

The goal of education is to enlarge and extend the many functional neural networks of the brain for greater storage and processing of information. Such networks cover a wide range of content: language, culture, history, art, music, science, feeling states, religion, mathematics, communication, etc. A fully educated brain contains innumerable hooks for attaching, rearranging, and using the information accumulated in the memory system. It can identify problems and solve them. The brain is attuned to profit by history, by knowledge of the great religions, and by the roles that feeling states and culture play in the affairs of man. Education strives to develop a brain capable of enjoying the day and to improve the capacity of the brain to tolerate without hostility the belief systems and behavior of other persons. Education can make the day more enjoyable and the outcome of education is useful when it creates attitudes and feelings that make the day more meaningful. The educational process is not necessarily related to the production of useful things.

Training develops the neural pathways formed by education into well-grooved and well-worn tracks that permit repetitive performances with a high degree of efficiency. Training is aimed at the formation of habits which are so ingrained by repetition that only a minimal outlay of nervous energy is required for performance. Training leads to efficiency over a narrow spectrum; education leads to a broader spectrum of competency.

High school, college, the early years of medical school, and experiences in research laboratories are oriented toward education. Internships and residencies are designed to train the doctor to perform repetitious tasks efficiently. Many postgraduate posts combine research (education) with clinical activities (training).

Our high schools tend to be divided into those that prepare students for college and those that prepare students for direct entry into the work force. The latter are called vocational schools. The graduate from either type of high school will move to areas where it is hoped he will continue to learn. The graduate from high school entering the work force will be trained on the job to perform tasks required by his work. In most instances there will be little time for structured educational programs. His continued education depends on individual effort in an unstructured environment. The only educational capital he has is that obtained during his high school years. He pays a penalty if his vocational high school has sacrificed education for training.

The high school graduate going to college has a better chance of continuing his education, depending on whether the faculty of the college he has selected comprehends the difference between the words *education* and *training*. Eventually the college graduate enters the work force. If his brain has been altered in a favorable way by his college experiences he will be quicker to see opportunities beyond his first job. His college education should protect him to some extent from the rapid changes of our modern society and technology.

At high school graduation we hope that the student has the following attributes:

1. A picture of himself as one who is capable of earning a living in our society.
2. An ability to enjoy the day and not resent the fact that others can legitimately make demands on him.
3. The ability to work with concentration at a task until it is complete.
4. An awareness of time in terms of punctuality and as a measure of efficiency.
5. An appreciation of the fact that the teacher as well as the student has problems.
6. The ability to read English with speed and comprehension. He should be able to understand written instructions quickly and correctly.
7. The ability to communicate accurately by written and spoken word.
8. A quantitative sense which allows him to use mathematics to solve problems and to make accurate measurements.
9. An overview of the arts and sciences which allows him to comprehend books in these areas written for the general public.

From Box 3910, Duke University Medical Center, Durham 27710.

10. An adequate knowledge of history which lets him know the complexity of our social, political and economic systems.

11. An ethical sense which distinguishes between right and wrong and supplies a framework for continued personal growth.

A high school graduate with this educational background can enter the work force of modern society free from fears of obsolescence. Education, not training, protects his future.

Vocational education was formalized because a number of students did not appreciate the need for an educational program and wished task-oriented training which would equip them to earn immediate income. We have always had this problem in medical schools. Some students want to learn only those aspects of biomedical science that are most quickly applied to clinical problems. In the clinical years they wish to be trained for clinical tasks rather than to explore new areas of knowledge which will be applicable clinically in later years. The wise instructor uses the least amount of task-oriented material that is compatible with holding the attention of the student. He leads the student to explore knowledge tangential to the current task and which prepares the student for the future. The faculty know that in most instances the total intellectual capital of the student will be accumulated before he enters private practice. Training continues in practice but education frequently stops.

A recent publication of the National Academy of Sciences[1] entitled *High Schools and the Changing Work Place* addresses the differences between education and training. It emphasizes the weakness of the predominately vocational approach and urges that today's high schools guard against selling the student's educational birthright for a mess of vocational porridge.

Reference

1. High Schools and the Changing Workplace. The Employers' View. Report of the Panel on Secondary School Education for the Changing Workplace. National Academy Press, Washington, D.C., 1984

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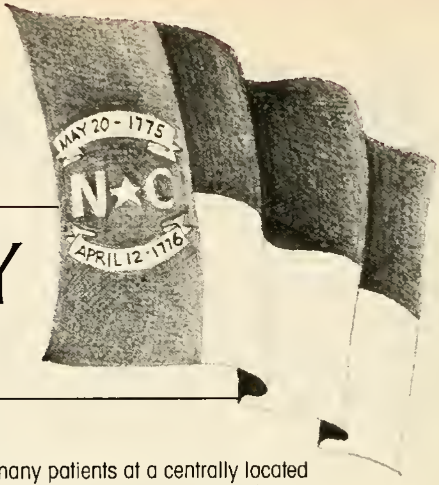

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Dr. Gaine Cannon

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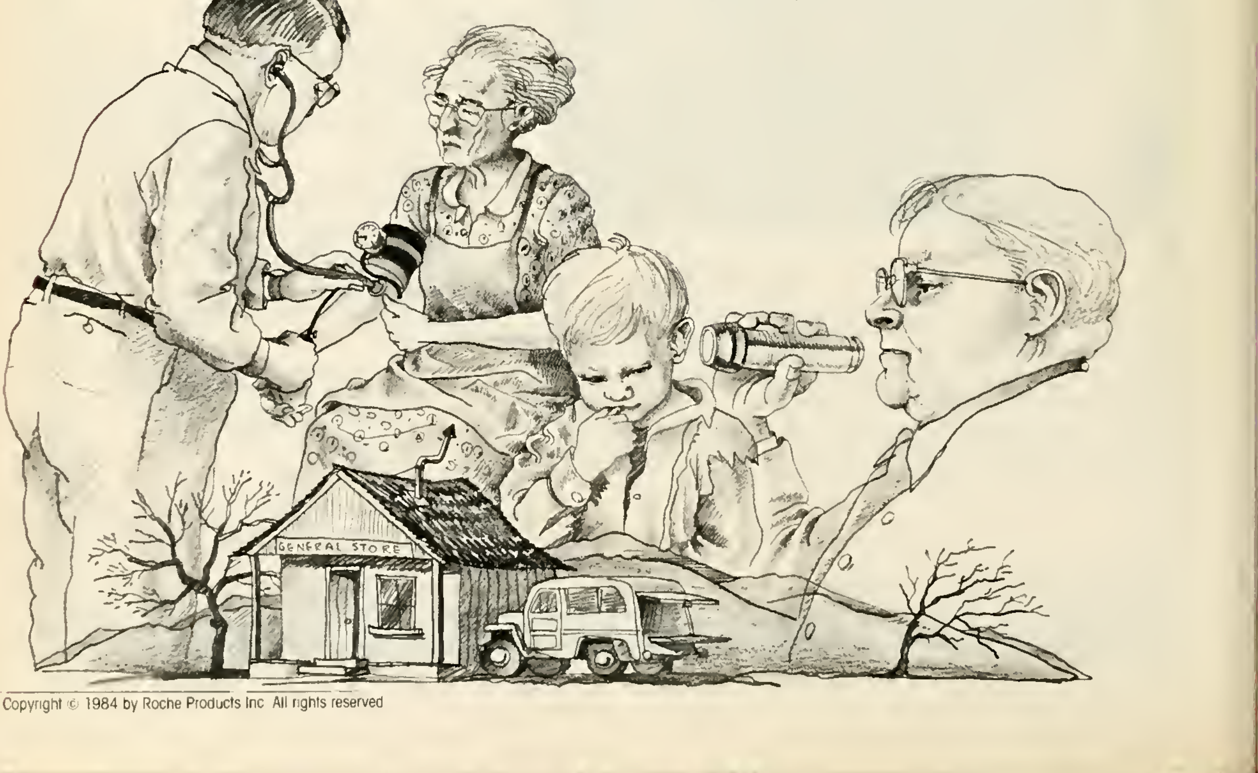
At all hours

But emergencies often interrupted his sleep. Dr. Cannon claimed his real office hours were 24 hours a day, and his patients revered him for it.

Dr. Cannon died in 1966 at the age of 68. He will be long remembered—most especially by the more than 5000 North Carolinians he helped bring into the world, some of them at the side of a rutted country road.

Reference: 1. Doctor in the backwoods, in Lee RV, Eimerl S *et al* *The Physician* New York, Life Science Library, Time Inc , 1967, pp 38-50



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In two multicenter studies, only 1.9% of Limbitrol patients experienced cardiovascular side effects.[3]

Patients should be cautioned about the combined effects with alcohol or other CNS depressants and about activities requiring complete mental alertness such as operating machinery or driving a car.

References: **1.** Rickels K: Drug treatment of anxiety, in *Psychopharmacology in the Practice of Medicine*, edited by Jarvik ME, New York, Appleton-Century-Crofts, 1977, p 316 **2.** Feighner JP *et al* *Psychopharmacology 61* 217-229, Mar 1979 **3.** Data on file, Hoffmann-La Roche Inc , Nutley, NJ

In moderate depression and anxiety

Limbitrol® Ⓒ IV

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LIMBITROL® Tablets Ⓝ Tranquilizer–Antidepressant

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Indications: Relief of moderate to severe depression associated with moderate to severe anxiety

Contraindications: Known hypersensitivity to benzodiazepines or tricyclic antidepressants Do not use with monoamine oxidase (MAO) inhibitors or within 14 days following discontinuation of MAO inhibitors since hyperpyretic crises, severe convulsions and deaths have occurred with concomitant use, then initiate cautiously, gradually increasing dosage until optimal response is achieved Contraindicated during acute recovery phase following myocardial infarction

Warnings: Use with great care in patients with history of urinary retention or angle-closure glaucoma Severe constipation may occur in patients taking tricyclic antidepressants and anticholinergic-type drugs Closely supervise cardiovascular patients (Arrhythmias, sinus tachycardia and prolongation of conduction time reported with use of tricyclic antidepressants, especially high doses Myocardial infarction and stroke reported with use of this class of drugs) Caution patients about possible combined effects with alcohol and other CNS depressants and against hazardous occupations requiring complete mental alertness (*e g* , operating machinery, driving)

> ***Usage in Pregnancy:*** **Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.**

Since physical and psychological dependence to chlordiazepoxide have been reported rarely, use caution in administering Limbitrol to addiction-prone individuals or those who might increase dosage, withdrawal symptoms following discontinuation of either component alone have been reported (nausea, headache and malaise for amitriptyline, symptoms [including convulsions] similar to those of barbiturate withdrawal for chlordiazepoxide).

Precautions: Use with caution in patients with a history of seizures, in hyperthyroid patients or those on thyroid medication, and in patients with impaired renal or hepatic function Because of the possibility of suicide in depressed patients, do not permit easy access to large quantities in these patients Periodic liver function tests and blood counts are recommended during prolonged treatment Amitriptyline component may block action of guanethidine or similar antihypertensives Concomitant use with other psychotropic drugs has not been evaluated, sedative effects may be additive Discontinue several days before surgery Limit concomitant administration of ECT to essential treatment See Warnings for precautions about pregnancy Limbitrol should not be taken during the nursing period Not recommended in children under 12 In the elderly and debilitated, limit to smallest effective dosage to preclude ataxia, oversedation, confusion or anticholinergic effects.

Adverse Reactions: Most frequently reported are those associated with either component alone drowsiness, dry mouth, constipation, blurred vision, dizziness and bloating Less frequently occurring reactions include vivid dreams, impotence, tremor, confusion and nasal congestion Many depressive symptoms including anorexia, fatigue, weakness, restlessness and lethargy have been reported as side effects of both Limbitrol and amitriptyline Granulocytopenia, jaundice and hepatic dysfunction have been observed rarely

The following list includes adverse reactions not reported with Limbitrol but requiring consideration because they have been reported with one or both components or closely related drugs·

Cardiovascular Hypotension, hypertension, tachycardia, palpitations, myocardial infarction, arrhythmias, heart block, stroke

Psychiatric. Euphoria, apprehension, poor concentration, delusions, hallucinations, hypomania and increased or decreased libido

Neurologic Incoordination, ataxia, numbness, tingling and paresthesias of the extremities, extrapyramidal symptoms, syncope, changes in EEG patterns

Anticholinergic Disturbance of accommodation, paralytic ileus, urinary retention, dilatation of urinary tract

Allergic Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus

Hematologic· Bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia

Gastrointestinal· Nausea, epigastric distress, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, black tongue

Endocrine· Testicular swelling and gynecomastia in the male, breast enlargement, galactorrhea and minor menstrual irregularities in the female, elevation and lowering of blood sugar levels, and syndrome of inappropriate ADH (antidiuretic hormone) secretion.

Other· Headache, weight gain or loss, increased perspiration, urinary frequency, mydriasis, jaundice, alopecia, parotid swelling

Overdosage: Immediately hospitalize patient suspected of having taken an overdose Treatment is symptomatic and supportive. I V administration of 1 to 3 mg physostigmine salicylate has been reported to reverse the symptoms of amitriptyline poisoning See complete product information for manifestation and treatment

Dosage: Individualize according to symptom severity and patient response Reduce to smallest effective dosage when satisfactory response is obtained Larger portion of daily dose may be taken at bedtime Single *h s* dose may suffice for some patients Lower dosages are recommended for the elderly

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PHYSICIANS' FORUM

Cost Containment

Eugene W. Linfors, M.D., editor

The question for September is: **What approaches to cost containment have been successful in your practice?**

From Dr. James E. Davis, a surgeon in Durham.

The following four items are those which have perhaps been most productive in my practice.

1. **Keeping patients out of the hospital.** This, of course, is the greatest increment in total health care costs, and with extensive use of ambulatory surgery, literally hundreds of thousands of dollars have been saved, without sacrifice of quality of care, and almost without exception to the greater pleasure and comfort of the patient. Ambulatory care, of course, is not limited to surgery, and its more extensive use in all fields should be encouraged.
2. **Obtaining necessary diagnostic and laboratory studies prior to hospital admission.** This saves preoperative days in the hospital and actually allows for a better patient evaluation, since any questionable determinations can be repeated, if absolutely necessary, without extending a hospital bill. Again, such prior-to-admission studies are applicable to every field, except for true emergencies.
3. **Anticipating hospital discharge date and discussing it thoroughly with the patient.** Patients' attitudes and understanding of avoiding unnecessary hospitalization have improved in recent years. They appreciate and try to cooperate in arranging to leave the hospital at the appropriate time if this has been thoroughly discussed with them.
4. **Obtaining all current laboratory and radiological determinations from the referring physician.** Though this may require additional time and effort in calling or writing the referring physician's office, it avoids duplication of services and charges.

From Dr. John Glasson, an orthopedic surgeon in Durham.

The doctor members of our professional corporation are acutely aware of the necessity for cost containment in medical care, and we are employing a number of strategies.

To begin with, we are cooperating with the American Medical Association and North Carolina Medical Society in agreeing not to increase our fees for the next year.

We are attempting to minimize patient days in the hospital by initiating discharge planning under the auspices of the Social Service Department at the time patients are admitted. We are also endeavoring to make appropriate use of extended care facilities when needed, and the hospital is enlarging its home health care program in a further effort to promote early discharge from the hospital and a continuum of care in the home setting.

Increased facilities for home health care seem to carry the greatest potential for cost savings when provisions are made for the administration of, for instance, intravenous antibiotics on a long term basis rather than keeping the patient in the hospital for these treatments. Other similar high tech procedures on a home health care basis will offer similar potential for cost savings.

We are also taking care to avoid duplication of laboratory studies and x-rays and are attempting to provide these items for patients on an outpatient basis before being admitted to the hospital in order to avoid the necessity for doing the tests after admission to the hospital. We are also perhaps saving some by using commonly available household items such as old tennis shoes cut out and placed over casts rather than using commercially provided cast shoes purchased in the hospital. We are also attempting to minimize use of disposable items in the hospital as much as possible in instances where safe and effective care for the patient is not compromised.

Our hospital also periodically provides computer printouts of bills for patients' individual doctors in order to acquaint the physician with charge levels for all items and also with the total cost of medical care for typical diagnoses.

In the operation of our professional corporation, we are trying to avoid productivity targets for our physician members, since these tend to put a premium on maximization of charges for the individual patients in order to maximize the individual physician's income.

Probably the most basic effort that we make in trying to contain costs is to maintain at all times the best possible physician-patient relationship. The breakdown of good physician-patient relationships has the potential for creating litigation and the now rapidly escalating premiums for professional liability insurance. These premiums, as you know, are again threatening to produce the failure of one of our professional liability insurance companies and are driving physicians out of certain types of specialty practice or, indeed, entirely out of any practice.

The effort at tort reform in our state legislatures promoted by Medical Society activity in recent years no longer seems to be the answer. It appears that the public must come to realize that these astronomical costs for professional liability insurance are simply passed through in the physicians' charges and it, indeed, is a problem for the public as well as for providers of medical care. Some approach through our medical-business coalition or through business roundtables could be productive.

Our legislatures are not very sympathetic with the financial plight of physicians with six figure incomes, even when they do have to pay astronomical professional liability premiums. The problem is that the premiums themselves are now approaching five figures in some states.

From Dr. Ira M. Hardy II, a neurosurgeon in Greenville.

As Chairman of the Cost Effective Medical Care Committee for the state Medical Society, I have a strong opinion that outside forces such as medical business health coalitions will have the greater impact on health care cost containment than other cost conscious activities.

As far as my own practice is concerned, our office has adopted the fee freeze requested by The American Medical Association and endorsed by The North Carolina Medical Society. Our office makes an effort to get third party state-supported systems to cover all eligible people whether they are insured or not. This tends to keep the fees charged to these particular people within the guidelines of reimbursements established by that State agency. I am referring to agencies such as Vocational Rehabilitation and Crippled Children.

Our office makes every effort to obtain as many outpatient diagnostic evaluations as we can and we do a considerable amount of ambulatory surgery for minor operative procedures such as surgical treatment of carpal tunnel syndromes.

From Dr. F. Maxton Mauney, Jr., a cardiovascular surgeon in Asheville.

My initial response to this question would be to emphasize the extremely beneficial and "time-effective" utilization of Physician Assistants in our private group tertiary care practice for the past fourteen years. Historically, surgeons have assisted one another during major operative procedures and third party insurers have often paid an "assistant's fee" of approximately twenty percent of the standard surgical fee. We followed this model for many years but as our experience grew and as our volume increased, we began to utilize out of necessity our PAs as first assistants in the operating room. Since third party reimbursement groups would not pay for those PA first assistant services, even at a reduced rate, we did adjust our fees upward to some extent in order to cover a portion of the PA's salary and indirect cost overhead. We have found with increased utilization of very talented, skilled, and experienced PAs that our overall surgical throughput was considerably enhanced. More importantly, with increasing experience we have found that the PA in our practice not only contributes to the overall effectiveness with which an operation is performed, he or she can help shorten the operating time by division of labors! (Saphenous vein harvesting while the surgeon is opening the chest and cannulating the patient, etc., or closing secondary incisions, etc.) While it is very difficult to document an absolute cost saving in this regard, there is no question in my mind that it has been an effective utilization of relatively less expensive medical manpower. Many residency programs have discovered this in recent years.

I became much more personally sensitized to cost effective measures several years ago while serving as a Commissioner of the North Carolina Medical Society, at which time I was heavily involved with the re-organization of our Society's Committee on Cost Effective Health Care, so ably chaired by Dr. Ira Hardy. One of the simplest things that occurred to me as the Blue Cross/Blue Shield Regional Hospitalization Utilization Data were presented, was to consider our habit of preadmitting patients for major open heart surgery *two days* in advance of the scheduled surgical date. A little over a year ago we shortened our preoperative in-patient stay by one day for cardiac surgical patients. Whereas we formerly brought a patient in two days before surgery so that intensive preoperative laboratory testing and in-depth orientation by physical therapy, inhalation therapy, ICU nursing staff, and others could be provided, we now do much of this on a pre-admission basis and all of it is accomplished within twenty-four hours of surgery. At the time our open heart surgery case load passed three hundred we implemented this shorter hospital stay and have effected considerable cost savings. This simple step has saved over three hundred in-patient days in the past year alone.

Another new program that I have observed in this community has been the establishment of an ambulatory intravenous drug program. This has been extremely successful. Patients who formerly remained in the hospital for anywhere from four to six weeks for intravenous antibiotic therapy associated with endocarditis or valvulitis can now go home many weeks ahead of time and be followed either by our group or the cardiology group and our infectious disease colleagues. It not only has saved money, it has made the patient's lifestyle much more pleasant and tolerable in many instances.

Now, at the risk of being on the receiving end of considerable heat, I would point out one other evolving practice pattern that has disturbed me for years. This is a pattern that exists in communities in the state that usually have a relative doctor surplus, and fortunately it is not a major problem in Asheville. This is a pattern wherein the patient's primary care physician (used in a generic sense) makes an appropriate diagnosis on an ambulatory basis that clearly calls for a standard surgical intervention. That patient is usually seen by the surgeon but lo and behold is then admitted by the referring physician, has a complete comprehensive hospital "workup" and is seen daily preoperatively and postoperatively usually up to the time of discharge by one or more internists, family practitioners, etc. I can understand this in patients who have impaired reserves involving different organ systems. It then becomes a medical necessity and a wise and prudent involvement of associates. However, I do feel that specialists in surgery should be able to admit a patient on their own, do a competent medical workup, operate on that patient and take care of the usual and common postoperative problems without having to get into what I call practicing medicine by committee. There is no question that the patient today benefits substantially from the input of expert consultants from a variety of fields when that patient has multisystem dysfunction. However, all of us need to *learn* some of the care principles that our consultants in infectious disease, pulmonary medicine, cardiology, nephrology, endocrinology and other specialized fields teach us as they work in a collaborative relationship. A heightened sense of what this means in terms of cost came home to me in a personal way after my father was hospitalized for major pulmonary surgery. He developed postoperative complications and I am eternally grateful for the care he received by a team of physicians which included a cardiologist, a pulmonary medicine specialist, a nephrologist, and my own surgical colleagues. However, it became quite obvious that twice a day visits to the Intensive Care Unit, while appropriate and very much appreciated, can and do result in substantial increases in professional fees to the individual patient. I think it behooves all of us to be aware of this and to convene multiple disciplinary M.D. care teams when it is truly indicated.

Finally, I would point out that recently we have seen a number of "grocery lists" of so-called "approved" ambulatory surgical and diagnostic procedures that have come from a variety of reimbursement groups. It is quite conceivable for a physician to go through a complete Certificate of Need, build an ambulatory surgical center, apply for and get a license and then start to do innovative and new ambulatory surgical procedures and not be reimbursed by Medicare or Medicaid in his/her surgicenter simply because the procedures that the physician decides can be done less expensively are not on the Federal Registry approved schedule. Likewise, a number of Blues and other commercial carriers have sent out sample lists of procedures that will not only be paid for on an ambulatory basis, but will be paid for in spades. These lists may leave out other procedures that might indeed be considered for less expensive ambulatory care. Thus, I continue to have a major frustration with those evangelistic cost containment proponents in that they complain about the problems and at the same time throw up enormous bureaucratic obstacles to innovative approaches on the part of physicians. Why not let physicians and surgeons decide for their patients what can be done safely, efficiently, and in a cost effective fashion outside the hospital and then reimburse that physician fairly for his innovative care?

From Dr. Jacqueline Pugh, a fellow in internal medicine in Durham.

Residents in a private hospital often feel as if they have little control of spending on the private patients for whom they care. Each of my three years here at Duke revealed to me ways in which I directly added to costs or, conversely, contributed to significant savings:

seeing chronically ill clinic patients frequently and regularly in an effort to prevent frequent emergency room visits and hospitalizations;

working closely with visiting home nurses and physical therapists to identify new or worsening problems before they require hospitalization;

never ordering "routine" admission studies but instead ordering only those tests necessary to diagnosis or management of that particular patient;

spending an extra hour or two on the telephone to schedule diagnostic tests prior to admitting a patient so no time in the hospitalization is wasted;

providing work and home phone numbers to my sickest clinic patients to try to decrease emergency room visits;

using the telephone to track down previous study results on referred patients thereby cutting down on repetition;

discussing patient progress with nurses, respiratory therapists, physical therapists, etc. in an effort to tailor care effectively to the individual patient;

filling out funding and placement forms speedily.

From Dr. John Stratton, an internist in Durham.

I believe the medical profession in general has not "come to grips" adequately with medical costs; there is much talk about cost containment, but little changes from year to year. I suggest some principles from the perspective of a primary care internist. I know what I do; I cannot be certain what is *effective*, since I cannot document *my* costs and outcomes.

1. The first requirement is a change in attitude. We must believe that costs really are very high for most patients. We must believe we can influence those costs, and try daily to limit costs.

2. More medical judgments are required as to what is *really* needed. A classic tool of medical education is the differential diagnosis. Too often we conclude our responsibility is to "rule-out" everything on the differential. Its purpose is for our *thinking;* but then we must make careful choices as to what we really think is wrong, what tests are most important, and what will influence our management.

3. Medical care should be viewed as continuing through time. A remarkable number of complaints resolve with time. It is easy to justify many tests to define the basis of symptoms, but we have no obligation to resolve all problems *now*. Over and over I tell patients I don't know what is wrong, but they are not seriously ill *now;* I will reevaluate the symptom next week, or next month; certain tests are indicated if the symptom persists; and meanwhile I'm available if the situation changes. This clearly involves risks, and living with uncertainty, but it is also based on training, knowledge, and experience.

4. In-patient and out-patient care should be a continuum. I regularly take some of a patient's office record to the hospital to document past problems and tests, and this may bypass some repeat tests. I often complete some tests as an out-patient that could easily have justified another day or two in the hospital.

5. Our profession *and* our culture must give special attention to medical decision making for very elderly patients. We doctors do too many tests, operations and treatments on debilitated patients that do not contribute to meaningful life. I am convinced that most patients and families are willing to discuss this and are willing to consider *not* doing what might be easily justified.

6. We need additional concern about medications. Some patients spend amazing amounts on medicines. I regularly review all medicines and plead with patients to bring them regularly. Often there are cheaper alternatives, doses and frequencies can be reduced, some medicines can be stopped, P.R.N. medicines are used excessively, and there

are often non-medication alternatives.

7. Doctors need to work harder on lifestyle changes — inactivity, obesity, smoking, tension, etc. Indeed, it is frustrating and the results are poor, but I believe it is essential if we are serious about reducing costs. Respiratory complaints are remarkably reduced without smoke; I have stopped many blood pressure and diabetic medicines after a modest diet and weight change.

• EDITOR'S NOTE: These opinions suggest to me that there are at least four ingredients for successful cost-containment strategies: an appropriate attitude to appreciate the need to contain costs; the common sense to think of useful changes in diagnostic and therapeutic strategies; an ability to make decisions under conditions of uncertainty; and the existence of proper financial incentives. I know from my experience at a university hospital that strategies to teach cost-effective health care have very little impact if any of the ingredients are missing. We would appreciate hearing any comments from our readers on this important subject.

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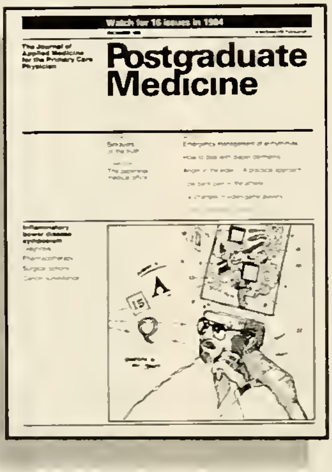

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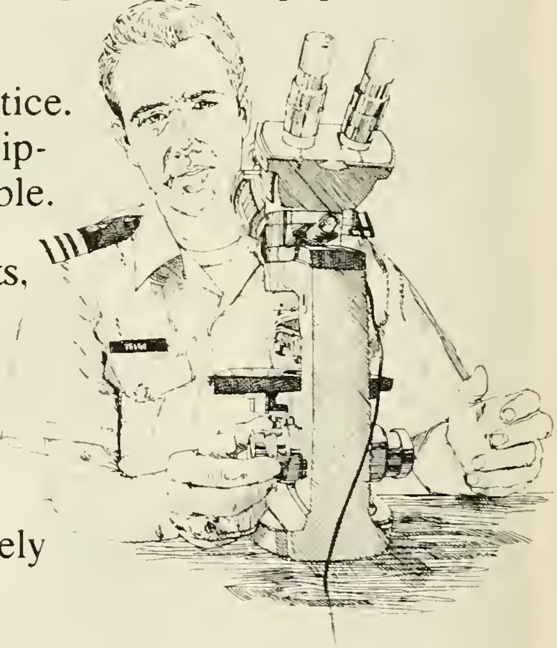

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MEDICAL EDUCATION

Partners in Education: The Academic Medical Center and the Community Hospital

Galen S. Wagner, M.D., Thomas T. Long, M.D., Thomas A. Reichert, M.D.,
Millard W. Wester, Jr., M.D., Clark M. Kerr, M.D., Clark Bishop, M.D., Charles F. Blackburn,
G. Reginald Tucker, Jr., M.D., Virginia Pact, M.D.

The Duke Cabarrus Medical Education Program*

Galen S. Wagner, M.D.

Thomas T. Long, M.D.

It is desirable to have continuing mutually beneficial interaction between physicians in practice and those in the academic medical centers who are responsible for training new physicians. As capable physicians complete training and move into adjacent communities, the patterns of patient referral to the academic medical center change, often resulting in a change of the patient population available for house-staff training. Likewise, diminishing federal funds are influencing programs to alter patterns of training. Supplemental programs for house-staff training would be helpful, particularly if they expose the trainees to patient populations not regularly seen, and if they simultaneously provide additional funding for the medical center.

Physicians in private practice are continually challenged to upgrade their diagnostic and therapeutic skills because of the rapid development of new technologies. Effective continuing educational programs are needed. Ideally these programs should not require travel or time lost from practice. As the practitioners gain new skills and knowledge, earning power increases. A portion of these earnings could be returned to the academic medical center to support the training of new physicians in return for the establishment of a continuing educational program in the community utilizing senior trainees and faculty.

This report describes a successful educational relationship between an academic medical center and a local community hospital. The Duke/Cabarrus Medical Education Program, over the eleven years of its existence, has had an important impact on the trainees, the medical center, the practicing physicians, and the community hospital.

In the early 1970s when the general physicians in the community hospital in Cabarrus County had determined their need for additional continuing medical education, they decided to establish an educational affiliation with the Duke University Medical Center.

The situation had several unique elements. 1) Many of the Cabarrus County physicians had been products of the Duke University Medical Center. 2) Eugene A. Stead, Jr., who had voluntarily retired from Chairmanship of the Department of Medicine in 1968, was available to turn his attention outside the doors of the academic medical center toward the development of other programs. 3) The Cannon Foundation, which had traditionally supported Cabarrus Memorial Hospital and the provision of high quality, cost effective health care, had also expressed a desire to develop an effective continuing medical education program. The Cabarrus physicians used Dr. Stead's time to help develop a program that would use the resources of the Cannon Foundation to create an educational affiliation which began in 1973 and which has survived and grown through all the changes of the academic medical center-community hospital relationships until the present.

The academic medical center needed funds to train subspecialty fellows, the fellows needed a workshop in the community hospital to develop their consultative skills, and the general physicians in the community hospital needed the on-the-job training these subspecialty fellows could provide them. Beginning in July 1973, fellows from five of the divisions of internal medicine began to travel for two 48-hour periods per month to function as educational consultants to the general internists at Cabarrus Memorial Hospital. In return for having a consultant present for one

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* The authors wish to acknowledge the assistance of Ladd W. Hamrick, M.D., Robert L. Wall, Betty C. Steele, R.N., and S. Spence McCachren, M.D., in preparing this report; and Sandra Gilmore and Gail McKinnis in preparing the manuscript.

24-hour period per week, the community hospital, through funds provided by the Cannon Foundation, supported the entire stipend for that fellow's training. Dr. Stead had advised that education programs between academic medical centers and community hospitals more often failed than succeeded because the academic centers did not require sufficient funding for these programs. He felt that the academic medical center would only be interested in continuing this program over time if the amount of money received were sufficient to compete with other potentially available funding sources. Physician scientists in the leadership roles in the academic medical center would only support the community hospital educational affiliation by providing the time of their fellows if, as in the novel *The Godfather*, "there was an offer they couldn't refuse."

Over the twelve years of its existence, the educational affiliation between Cabarrus Memorial Hospital and Duke University Medical Center has grown in many ways. Though this report relates only to the program in internal medicine, there were also programs in general and thoracic surgery, urology, orthopedics, otolaryngology, obstetrics and gynecology, and pediatrics, which continue to the present. Programs subsequently developed in pathology, psychiatry, and radiology. The community physicians are now matching the contributions of the Cannon Foundation and thus contributing their own generous financial support to the program. A unique aspect of the program is that the educational consultations are provided with no charges to the patients. Cabarrus Memorial Hospital has become the site of one of the regular senior assistant residency rotations in internal medicine. New and excellent generalists and specialists have moved into the community, many because of the existence of the educational affiliation.

Two full-time members of the Duke University Department of Medicine are based in the community to coordinate the activities of the residents and fellows. An additional full-time faculty member based at Duke travels one day per week to the community to assist in this coordination. The program is administered through the full-time activities of a former Director of Nursing In-service Education and her secretary at Cabarrus Memorial Hospital and the part-time activities of a staff assistant of the physician coordinator at Duke. As of July 1984, one fellow in each of the ten divisions of internal medicine at Duke is fully financially supported by educational consultative activities at Cabarrus Memorial Hospital.

The program at Cabarrus Memorial Hospital has served as a model for the development of educational affiliations between the Duke University Medical Center and ten other community hospitals in North Carolina and southern Virginia. North Carolina has participated in the Area Health Education Center (AHEC) program since the mid-1970s and this source has provided the primary funding for initiation of these other programs. The academic medical center realized that flexibility would be required both in the identification of funding sources and in program design in each community. After the medical center presented its concepts for these programs to the individual communities, time was required for sufficient barriers to be cleared so that the programs might be successfully implemented. Though the Cabarrus program was the model, other programs were not judged on their ability to duplicate that model but rather on their ability to fit comfortably within the context of that particular community's physicians and that particular community hospital.

Several reports in this issue of the *North Carolina Medical Journal* have originated from one of these community hospital programs spawned by this Cabarrus model. The Henderson program is different because it exists in a different medical community.

During the 1980s the survival ability of both the academic medical centers and the community hospitals will be challenged, primarily by the emergence of a hybrid institution: the large non-academic medical center with commitments to 1) as much general care as the traditional community hospital, 2) as much specialty care as the academic medical center, but 3) not as much academic activity in either research or education as the traditional academic medical center. These centers aspire to be all things to health care needs. However, they will produce a sterile medical society, because the physicians practicing in these institutions will be unable to either reproduce themselves or produce the knowledge required to determine the effects of the techniques they administer to their patients. Therefore, physicians practicing in these multifaceted medical centers have as great a stake in the success of the educational affiliations between the academic medical centers and the traditional community hospitals described in this report as do the physicians in these two differing but dependent institutions. Perhaps the reports in this issue of the *Journal* may serve to present the model of the Cabarrus program to the wider scope of the medical community and, thereby, to stimulate the question, "What can each of us do to assure the vitality of medical practice for the future?"

The Duke/Henderson Medical Education Program

Thomas A. Reichert, M.D.

In the state of nature, most successful organisms, both social and biological, exhibit territorial behavior. They succeed because they identify and defend territory in which they define a niche, a special role in the social/biological strata. In harmonious societies, aggressive behavior is at a minimum with most social and biological forces poised in postures which pressure all of the elements of the society back toward harmony and stability. In the 1930s, a theory arose to describe optimal behavior in competitive situations. Called A Theory of Games and Economic Behavior, this theory has been widely adopted in international political, in corporate, and even in interpersonal strategies. A fundamental result of this theory is that the strategy which produces a situation in which all parties have some power achieves the most peaceful and successful results. All parties gain most by cooperating. When aggressive behavior is initiated by any party, the most effective strategy is for all other parties to direct retribution against that individual, inhibiting his behavior and restoring harmony.

In the evolution of social systems, a cycle begins with the development of individuals with the capability and strength to interact with their immediate environment. This interaction ultimately brings them into contact with other individuals. Their initial interactions are usually aggressively competitive; and it is only after a period of negative reward that most systems settle into a pattern of cooperation. The pattern of growth of hospitals and medical centers in the United States has usually been one of a gradual development of individual institutions in relative isolation. Interaction has usually been at a distance with a clear division either in territory (in the case of institutions of equal facility) or in level of care (primary versus secondary/tertiary). The recent sharp rise in numbers of physicians has led to a wider availability of subspecialty skills and a concomitant increase in the quality and capability of hospitals in smaller communities. Some of the competition which has grown out of this strengthening has been aggressive and territorial. Less frequently, hospitals have joined together to seek, in cooperation, a union greater than its parts.

In this issue of the *Journal*, we will present a sort of testimony from a number of participants in a rather remarkable experiment. AHEC, Duke University Medical Center in Durham, North Carolina and Maria Parham Hospital in the town of Henderson some 40 miles away undertook an exercise in cooperation which began seven years ago. In the report of the Duke/Cabarrus program, Wagner and Long place in historical perspective some of the pressures that led the medical center to extend its resources into programs designed to be molded to the needs of neighboring communities. Millard Wester, M.D. has been the principal architect of the connection fashioned at the community level in the Henderson program. He describes for us the evolution of that interface as seen from the community's viewpoint. Our central theme is a portrayal of the attitudes and preconceptions that came to this project together with their evolutionary changes when both institutional parties learned the ways in which the various needs were served.

The mechanism used for medical center extension is a program where physicians in the late stages of their training in subspecialties of internal medicine provide consultation and other related resources in a community hospital where subspecialties of internal medicine are represented by only a very few practitioners. Through the traditional mechanism of case presentation, we will follow two patients as their medical conditions were recognized by their personal physicians and were shared with the consultant. As care needs exceeded those locally available, a program of augmented care was fashioned. In the first case the patient required physical transfer to the medical center where diagnostic and surgical facility not available in the community could be provided on an emergent basis. In the second case, a program of augmented care could be constructed and implemented at the community level. Medical center level expertise not economically plausible within the community because of limited need could, nevertheless, be made available on a limited basis sufficient to guide the personal physician in constructing an appropriate program. Each of the contributors has tried to present aspects of discovery and learning which this program of cooperation provided to them personally. Both patients and physicians have been asked to be as candid as possible.

Millard W. Wester, Jr., M.D., Henderson Coordinator, Henderson Outreach Program

There has long been a misconception that there are significant differences in medical opinion, practice and policy, and that a low level of cooperation is the natural relationship between "town and gown." In the belief that the end result of cooperation is likely to be better patient care, more efficiently delivered at a cheaper cost, a unique challenge arose to the "old folks" tale. A cooperative project designed to interweave the patterns of care at Maria Parham Hospital in Henderson and Duke University Medical Center in Durham was conceived in conversation in May of 1975 and put into practice in 1976. The initial concept was to create an extern program within Maria Parham Hospital. After discussion of many alternatives, we settled upon a resident consultant program in which a resident in medicine at Duke would visit our community, discuss referrals with doctors, interview and examine patients and then return to the medical center where he would consult with the senior staff members in the specialties that presented themselves in the patient's problems. The resident would then communicate back to the referring physicians either in person or by phone with suggestions for care and therapy. Senior staff members would also visit Maria Parham Hospital from time to time to more fully evaluate the course of the consultations and therapy.

Such a program was instituted in 1976; but after one year in that mode, the program was altered to better suit our needs. This alteration included the substitution of a number of fellows in several subspecialties of internal medicine. Cardiology, rheumatology, neurology, endocrinology, hematology, rheumatic diseases, and infectious diseases were originally included on a rotating basis. Because of the increased experience of the fellows, consultations could usually be accomplished and therapy outlined within the local hospital setting. Frequently, tests performed at the local hospital resolved a diagnostic dilemma without the patient having to leave our community.

Another bonus has been having a physician available who is familiar with the system at Duke Medical Center to help us make referrals and/or arrangements for studies expeditiously. With time and experience, we have found ourselves making outpatient referrals for studies that in the past required hospitalization, such as exercise tolerance tests, CAT scans and EEGs.

We are presently operating under this system with patients seen both as outpatients and as hospital inpatients. Pre-consultation information is supplied by the local doctor; and after seeing the patient, a person-to-person discussion is usually arranged between consultant and personal physician at which time diagnostic and therapeutic options are discussed. If emergent care or care exceeding local resources is required, transfer arrangements are made with the efficiency that only insiders can evoke. An added bonus to transferred patients is that they already have a Duke physician with whom they are familiar who will follow up their care when they arrive at Duke Hospital, report their progress and arrange their transfer back to local care.

Positive benefits of our program fall into three major areas: those to the patient, to the physicians at Maria Parham, and to the physicians at Duke.

Patient benefits derive from the faster, more efficient diagnosis and access to newer alternatives to traditional therapy. For example, in the field of cardiology, Maria Parham Hospital has not had to "gear up" to tests that could not be cost effectively utilized locally, including radionuclide scanning, cardiac catheterization and pacemaker placement. In a sense, our hospital becomes an extension of Duke's facilities for efficient utilization of these particular tests. Patients no longer need be admitted to Duke Hospital for evaluation prior to testing, but rather can be sent to the medical center only for the time period required for the testing or therapy.

Another positive effect on patient care is that a program of augmented care can often be created within the local community setting. This increase in level of care comes at a considerable saving both in the reduced cost of local hospital room and service charges and in the peripheral cost of transportation and family visitation to the more remote medical center.

Expeditious handling of emergencies with the help of the consultant physicians quickly replaces less effective referral mechanisms; and same day referral for non-emergent care has frequently been the rule. By comparison, there is usually a one or two week delay in scheduling admissions or even outpatient examinations, tests, or therapy for patients entered outside the consultant program.

Local physicians have also benefited in that their learning process for each patient has been expanded by the input from the consultant. The consultants have conducted a "Breakfast Club meeting" every other Tuesday morning at which time they spend one hour on some aspect of medical diagnostic care or disease processes. This small group setting has allowed for considerable dialogue and "honing in" on the areas of mystery or concern in some of our more common problems. The consultant physicians are also a resource for evaluation of hospital policies and practices. An excellent example is the input that our infectious disease consultant provided in aiding us to establish an effective program of infection control (see the article by Dr. Clark Kerr which follows). Policy has been re-examined in many of our patient care areas based on input from the consultant physicians with a savings that would be difficult to estimate.

To the fellows and physicians who have come to Maria Parham Hospital from Duke Medical Center, I would adjudge a positive benefit simply being that of first hand contact with the private practice of medicine. We have been pleased at the growing awareness that a high level of medical care can be delivered in such a community.

A new aspect of medical care that is being explored through this system is that of reverse referral. Patient care begun at the local hospital is occasionally complicated by a need for tests and/or therapy unavailable in the community. After transfer to the medical center for the acute need, the patient is referred in reverse back to Maria Parham Hospital as soon as stabilization permits resumption of local care. This mutual "vote of confidence" is not only good public relations for both hospitals but also efficiently utilizes the resources of both care centers, minimizing costs.

It is difficult to challenge aphorisms and "old folks" tales. This program has been a delightful opportunity to increase the cooperation of the local physician with the academic doctor. We have been particularly pleased with the early results of our program and feel that, with modification as appropriate to each local setting, this will become an important addition to the accepted way of delivering medical care. There have been rough spots, but the good has been real, the positive results have been many and all have been oriented to providing the best care for patients, which is after all the ultimate goal of any physician.

Thomas A. Reichert, M.D., Ph.D., Duke Coordinator, Henderson Outreach Program

The other contributors to this collection will stress the benefits which accrue to the patients and the physicians who care for them, both community and medical center based; but a cooperative outreach program has two additional entities as parties to the interaction. These are the two cooperating institutions; and like all parties to all other social and biological systems, the administrations of such institutions must clearly see mechanisms of benefit in such enterprises if their cooperation is to be whole-hearted and continuing. In July of 1981, I was offered the opportunity to coordinate the Henderson Outreach Program as an adjunct to my staff position at the medical center. Fresh from my own rewarding personal experience as a fellow in the program, I enthusiastically embraced the opportunity. Certain that the obvious benefits derived by patients and participating physicians were easily perceived by the administrations of both hospitals, I approached them individually only to find neither hospital's administration fully aware of the scope of the program and not entirely convinced of its benefits.

In the absence of a line of communication, any institution is inclined to a defensive outlook. The staff of the consultants' program, in concert with the physician community in Henderson, responded by providing nearly complete information on all consultations seen at Maria Parham Hospital and transfers to Duke Medical Center over the subsequent year. Based on admittedly sketchy data from preceding years, we found the rate of increase of consultations to be about 60% per year rising from 70 patients seen the entire first year of operation to 688 patients in the year 81-82. In this year, 600 of the 688 consultations were formal, leading to notes transcribed to the patient's chart; and 540 consultations involved direct patient contact as opposed to review of patient-related material. Three hundred of the 540 patients (56%) were outpatients seen through the emergency room and the remainder were seen as inpatients. Only 80 patients were actually transferred to the medical center for admission. Approximately two-thirds of these were inpatients at the time of their initial consultations. Thus, only about one consultation in seven actually led to a program of augmented care requiring transfer. All others could be managed locally.

The medical aspects were easiest to assay. Of the first 25 patients transferred to the medical center in that year, five became the subject for grand rounds either in general medicine or in a subspecialty conference. Because these patients were very ill, their length of stay exceeded one week; and their medical bills were correspondingly high. Nevertheless, the overall level of fiscal responsibility was demonstrated to be sufficient so that the consultants' program could operate unfettered by any need for financial screening.

At Maria Parham, we discovered that at least one-third of all consultations referenced the Neurology subspecialty, a fact previously unanticipated. Cardiology, with two consultants available, made up approximately another third of the consultation requests. Thus, as Maria Parham Hospital sought to enlarge its cadre of internists, the scope of their recruitment was broadened to include internists with either cardiology or neurology specialty training.

In addition to physician subspecialty utilization, the specific tests for which patients were referred to the medical center became available to both the administrations. Given the frequencies of referral, a cost effective approach to the acquisition of new laboratory equipment could be undertaken. Medical center consultation was made available in both evaluating new physician prospects and acquiring new equipment.

Finally, it was realized that no formal mechanism existed for coordinating and regulating the flow of patients in referral both to the medical center and, in reverse, to the community hospital. Administrative experiences at both institutions had never been organized so that a review of patient transfers could easily be made. A semi-formal mechanism has now been installed to record and assess the financial resources and medical requirements of each patient transferred between the two institutions. This history will provide a basis for future agreements. Approximately 90% of the referrals from the county surrounding Maria Parham Hospital to Duke Hospital still occur outside the Henderson Outreach Program. For these patients, no mechanism is currently available for coordinating local care and medical center care, which are thereby independent and sometimes conflicting.

The Henderson Outreach Program is a stable and viable enterprise. Each of the five participating entities — two hospitals, two sets of physicians and their patients — have come to see clear benefits to be derived from cooperation. Progress has been real, though we have often had to feel our way. There can be no doubt, however, that in the Henderson Outreach Program indifference and defensiveness have yielded to the nurture of the cooperative spirit.

Clark M. Kerr, M.D., Infectious Disease Consultant, Henderson Outreach Program.

Through the outreach program from Duke University Medical Center to the community hospital, Maria Parham in Henderson, I had the opportunity to visit one day every two weeks for the year July 1982 to July 1983. Initially, my only duty was to be available for consultation and clinical referrals, specifically in the subspecialty of infectious disease and, more generally, in internal medicine. While consultation remained a prominent part of my contribution at Maria Parham, it was in another role that I feel that the community was helped the most and was, in turn, most helpful and stimulating to my own training. This was the role I played on the hospital Infection Control Committee and, at times, on the hospital Pharmaceutical Committee. Shortly before my year began at Maria Parham, an accreditation review had cited several specific lacks in the protocol procedures for infection control at the institution. Working closely with the newly hired infection control nurse, we set about defining protocols for multiple areas relating to infection control within the hospital and the control of infectious disease more generally in the community. Some of the entities covered were 1) isolation procedures for infected post-surgical patients; 2) specification and clarification of isolation procedures for wound precautions; 3) dispensation rules for assigning placements within the hospital for patients with specific diagnoses; for example, adult versus pediatric wards, medical versus surgical wards, contaminated versus non-contaminated areas; 4) distinguishing colonization from infection. Sputum, tracheal aspirates and urinary tract infections were covered in detail.

At the time of my arrival, the staff at Maria Parham had identified the problem that their nosocomial infection rate appeared inordinately high. Upon investigating, I realized that it was primarily a lack of appropriate definition in protocols for infection control that caused the reported infection rate to be so high. Most cases of what was labeled infection and recorded as such in the hospital record were merely colonization. With understanding of the distinction between infection and colonization, new definitions could be applied and appropriate management procedures instituted. Subsequently, the nosocomial rate dropped dramatically at Maria Parham.

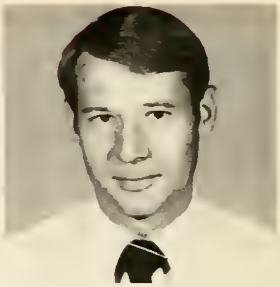
Other topics were taken up by the hospital Pharmaceutical Committee. These included the appropriate use of antibiotics, acceptable combinations of antibiotics, surgical prophylaxis with antibiotics, and recommendations for hospital formulary inventory of late generation antibiotic agents together with suggested restrictions for their use. These last issues had only just come under scrutiny at the time of my leaving Maria Parham and Duke University. We saw a large part of our mission as that of defining those areas of primary importance.

It was, I feel, a successful year both for myself and for the hospital. The hard evidence is the national board review which issued *no* citations this year at Maria Parham for standards of infection control and generally expressed delight with the progress made in the two years since the last review. I will be following with keen interest the reports of my successor in the consultant's role in infectious disease at Maria Parham.

Millard W. Wester, Jr., M.D., Practitioner, Family Medicine, Henderson, NC

Since returning to Henderson, North Carolina in 1953, I have furnished medical care and advice for my friend and neighbor, Mr. Charles Blackburn. Indeed, we have been friends since early childhood. I, therefore, have had the opportunity to see him for early phases of problems and to control and/or prevent difficulties before they reached severe proportions.

As early as 1965, Mr. Blackburn began to have episodic respiratory difficulty characterized occasionally by sputum production and, more recently, by bronchospastic wheezing. On most occasions he responded to the usual medication for "colds" including antihistamines and, occasionally, decongestants. On some occasions, antibiotics were prescribed because of changes in physical examination and/or laboratory findings as well as sputum changes. In 1980, he had an episode of bronchospastic wheezing severe enough to require prednisone treatment, the taper of which was most effective. It was noted since that time that he in fact responded rather poorly to antibiotics, but rather dramatically to prednisone taper doses. In April of 1983, he had two episodes rather dramatically difficult to control except with prednisone. Because these occurred so close together, I suggested that we have a consultation. Mr. Blackburn had already received good advice through the consultative services with the Duke consultant rheumatologist in the Henderson Outreach Program relative to controlling some of his arthritic symptoms. We quickly and mutually agreed that the pulmonary consultant in a local setting would be an excellent source for further information. As detailed in Dr. Bishop's report and in Mr. Blackburn's summary, we were able to elicit not only the reasons for his paradoxical responses to medication but, with further input, were able to shape a program which has been most successful in controlling almost completely this gentleman's difficulty to date. I am convinced that had we not had the availability of a consultant in the local setting providing expert information and advice without requiring the patient to give up so much of his professional time away from the office, we would have had difficulty persuading Mr. Blackburn to let us obtain a second opinion, and thereby alter the therapy so dramatically for his good response. In short, I think that this exemplifies the opportunity to conveniently access and treat early for the patient's better care in a most cost- and time-effective manner.



Clark Bishop, M.D., Pulmonary Disease Consultant, Henderson Outreach Program

I was asked to see Mr. Charles Blackburn in April 1983. He had been having episodes of sputum production accompanied by bronchospastic wheezing. He improved following steroid tapers but not after antibiotics. After having had several such episodes, Mr. Blackburn joked that as an attorney, he could not afford to get out of breath. Both he and his family physician, Dr. Millard Wester, were concerned that he might have developed an allergy to something. We had Mr. Blackburn come in for allergy testing and for pulmonary function tests. These studies revealed unimpressive allergic reactions to skin test antigens. Pulmonary function tests showed FEV 25-75 decreased to 41% of predicted values, suggestive of small airway obstruction. I discussed these results with Mr. Blackburn and Dr. Wester. Since the chances of improvement with immunotherapy were small we decided not to follow that avenue. We felt that he could get the benefit of steroid therapy using inhaled beclomethasone and we could avoid the systemic side effects of prednisone. It was then that Dr. Wester recalled that while Mr. Blackburn's alcohol intake was moderate, he nevertheless seemed worse after having a few drinks. We then devised a program of bronchodilator therapy, inhaled beclomethasone and steroid tapers only when necessary for exacerbations, as well as strict avoidance of alcohol. Mr. Blackburn has done very well on this regimen.

This case illustrates a blending of the art and science of medicine in a cooperative interaction between the referral hospital and the community physician. At the referral hospital we were able to provide data to suggest which methods of therapy would likely be helpful. Dr. Wester, the family physician, was able to discern nuances about Mr. Blackburn's case and made suggestions to optimize the care. Furthermore, Mr. Blackburn did not require hospitalization at the referral center and lost minimal time away from his law practice.

Charles F. Blackburn, Patient, Henderson Outreach Program

After examining me, Dr. Wester suggested I see the specialist from Duke. He set up an appointment, and when I went over to the local hospital to see him, I didn't have to wait. I went right on through. The Duke consultant performed some tests and evaluated them. Then he and Dr. Wester consulted about my case and prescribed what I should do.

First of all, it was a great convenience. I didn't have to go to Durham. Everything was done right here. The fee was incredibly low. I think it was $50. The fact that the specialist from Duke comes here seems to give him more time to consider each individual case, and the patient feels he's getting more personalized care. Plus, it's less physically demanding on the patient. I didn't have to go to Durham and worry about a place to park or worry about navigating through the medical center. Instead, I received expert care in familiar surroundings, just a few minutes from home.

Our second case illustrates how a cooperative interinstitutional system can be harnessed with speed and dispatch when an emergent condition arises. Our contributors, the interacting local personal physician and the outreach consultant, develop here insight into the specific changes the interrelationship has made in this aspect of the delivery of medical care in the community.

G. Reginald Tucker, Jr., M.D., Practitioner, Family Medicine, Henderson

In spite of modern transportation and communication, a primary physician in a small community can feel medically lonely and isolated in situations where diagnosis may be confusing and unclear. When such a situation arises in a crisis setting with a need for rapid evaluation and therapy, access to a large medical center can be very comforting. Just such a situation occurred recently when a young woman in generally good health was seen two weeks to the day after she had suffered a physical beating. She had been evaluated shortly following the incident and no serious consequences of her abuse seemed evident. She was re-evaluated several days later and then returned to her work as a skilled typist. Yet, on the day of the crisis she was brought in at our direction, drowsy, and with a headache, but coherent, oriented, and able to walk. There were only soft, suggestive neurological signs; but our exam raised serious suspicions. A call to the neurological consultant in the Henderson Outreach Program and a brief expression of our concern led to a rapid ambulance transfer directly from our office to the Duke Emergency Room where superb handling and rapid CT scanning confirmed the presence of a subdural hematoma of large size threatening tentorial herniation. Immediate neurosurgical intervention with burr holes and craniotomy resulted in a remarkable recovery.

The consultant program contributed to this successful outcome in several ways. The consultant was *known* to the physician and rapid direct contact was possible leading to smoother logistical handling of the case. The physician was *known* to the consultant who could thus more readily appreciate the concern and the evaluation presented. Having worked in the community, the consultant *understood* what technical facilities were (or were not) available and could also understand the dilemma of the local physician. Finally, the local physician had benefitted from ongoing update and refresher programs provided by the consultants (at Breakfast Club talks and through personal contact in the handling of individual patients), making the recognition of less frequently seen problems more prompt and accurate. It seems that all of the attributes of the consultants program were at work here and provided an immeasurable benefit to all concerned.

Virginia Pact, M.D., Neurology Consultant, Henderson Outreach Program

In September 1983, I received a call from Dr. Tucker in Henderson concerning a patient who had suffered head trauma two weeks previously. This young woman worked as a legal secretary and was a personal friend of the referring physician. She had been the victim of family violence and although she was still working, she complained of a very severe headache. Her headache had worsened in the last few days, and on the day I was contacted, she had not been able to go to work. Her physician called her at home and was concerned because she seemed so lethargic. He persuaded her to come to the office. She was indeed lethargic, but without focal findings. He felt she needed an emergency CT scan to rule out a subdural hematoma.

The patient was immediately transferred to the Duke Emergency Room for further evaluation. The neurology resident found her to be lethargic, but in addition noted that she had difficulty with eye movements and had left arm and leg weakness. Because of the lethargy and rapidly evolving focal signs, a CT scan was obtained emergently which showed a large left-sided acute and subacute subdural hematoma. The clot was evacuated by the neurosurgeons the same evening and the patient has done extremely well since then. (In passing, it is interesting to note this was a *left* subdural with *left* body weakness — an example of compression of the contralateral brainstem against the edge of the tentorium — the so-called Kernohan's notch.)

The successful outcome in this patient's case began with the recognition of the seriousness of her condition by her family physician. The development of the Duke outreach program has made it easier for the community physicians to contact the appropriate doctor, speak to him or her personally, and by that means arrange for specialist evaluation. This is particularly important in an emergency situation and indeed, proved life-saving in this patient's case.

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Bulletin Board

Continuing Medical Education

Please note: 1. The Continuing Medical Education Programs at Bowman Gray, Duke, East Carolina and UNC Schools of Medicine, Dorothea Dix, and Burroughs Wellcome Company are accredited by the American Medical Association. Therefore CME programs sponsored or cosponsored by these schools automatically qualify for AMA Category I credit toward the AMA's Physician Recognition Award, and for North Carolina Medical Society Category A credit. Where AAFP credit has been obtained, this also is indicated.

IN STATE

September 21
Sixth Annual Health Law Forum
Place: Greenville
Info: Mary Valand, Box 7224, ECU School of Medicine, Greenville 27834. 919/758-5200.

September 21-22
New Advances in the Treatment of Sickle Cell Disease
Place: Wrightsville Beach
Credit: 8 hours Category I
Info: Cindi Easterling, Box 3108, DUMC, Durham 27710. 919/684-6878.

September 28-29
Adolescent Health Issues: Challenges for the 1980s
Place: Durham
Credit: 9 hours Category I
Info: Cindi Easterling, Box 3108, DUMC, Durham 27710. 919/684-6878.

October 1-5
Nuclear Magnetic Resonance for the Imaging Team
Place: Winston-Salem
Credit: 30 hours Category I AMA
Fee: $500
Info: Richard Witcofski, Ph.D., Department of Radiology, Bowman Gray School of Medicine, Winston-Salem 27103.

October 1-5
Microsurgery Workshop
Place: Durham
Credit: 40 hours Category I AMA
Info: Jackie Brooks, Box 3372, Duke University Medical Center, Durham 27710. 919/684-3347

October 3
Practical Solutions for Common Medical Problems
Place: Research Triangle Park
Credit: 6 hours Category I AMA
Info: Kathy Hundley, Educational Services Coordinator, Burroughs Wellcome, Research Triangle Park 27709. 919/248/4904

October 3-4
24th Annual Charlotte Postgraduate Seminar
Place: Charlotte
Credit: 16 prescribed hours AAFP
Info: J. Lewis Sigmon, Jr., M.D., Box 32861, Charlotte 28232. 704/331-3172

October 5-7
Practical Problems in Arthritis Management
Place: Wrightsville Beach
Credit: 9 hours Category I AMA
Fee: $65
Info: NC Chapter of the Arthritis Foundation, Box 2505, Durham 27705. 1/800/672-0949

October 13-14
Radiology Mini-Course in Abdominal Imaging
Place: Durham
Credit: 10 hours Category I AMA
Info: Cindi Easterling, Box 3108, Duke University Medical Center, Durham 27710. 919/684-6878

October 24-27
Fall Seminar, American Academy of Clinical Anesthesiologists
Place: Asheville
Credit: 11 hours Category I AMA
Info: AACA, Knoxville, TN 37919-1691. 615/588-6279

October 26-27
Psychopharmacology: Practical Drug Treatment of Psychiatric Disorders
Place: Chapel Hill
Credit: 10 hours Category I AMA
Fee: $125
Info: Nancy Williams, Department of Psychiatry, UNC School of Medicine, Chapel Hill 27514. 919/966-4738

October 26-27
Advanced Cardiac Life Support Instructors Course
Place: Winston-Salem
Credit: 20 hours Category I AMA and ACEP
Fee: $250
Info: Earl Schwartz, M.D., Emergency Medicine, Bowman Gray School of Medicine, Winston-Salem 27103.

November 1-2
Current Topics in Urology
Place: Chapel Hill
Credit: 13 hours Category I AMA
Fee: $125
Info: Barbara Judd, 428 Burnett-Womack Building 229H, Chapel Hill 27514. 919/966-2571

November 11-14
Advanced Clinical Teaching Skills
Place: Rougemont
Credit: 20 hours Category I AMA and AAFP
Info: Katherine Munning, 407 Crutchfield Street, Durham 27705. 919/471-2571

December 4
Duke Tuesday
Place: Durham
Credit: 5 hours Category I
Info: Linda Mace, Box 3707, Duke University Medical Center, Durham 27710. 919/684-2033

OUT OF STATE

September 20
Use of Computers in the Medical Office
Place: Johnson City, TN
Credit: 6 hours Category I AMA
Fee: $60
Info: Sue Hutchinson, Quillen-Dishner College of Medicine, Johnson City, TN. 615/928-6426, ext. 204

October 12
Selected Topics in Pediatrics
Place: Norfolk, VA
Info: Jean E. Shelton, M.D., Children's Hospital of the King's Daughters, 800 West Olney Road, Norfolk, VA 23507. 804/628-3798

October 18-25
Review of Clinical Chemistry Seminar
Place: San Diego, CA
Credit: 40 hours Category I AMA
Fee: $315
Info: Mary Valand, Box 7224, ECU School of Medicine, Greenville 27834. 919/758-5200

October 20-27
4th Diving Accident and Hyperbaric Oxygen Treatment
Place: Grand Cayman, BWI
Credit: 26 hours Category I AMA, AAFP, ACEP
Info: Cindi Easterling, Box 3108, Duke University Medical Center, Durham 27710. 919/684-6878

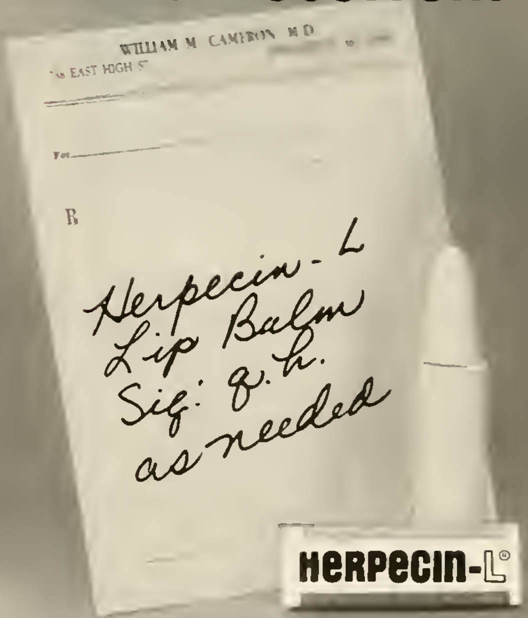
October 22-26
Postgraduate Course in Diagnostic Imaging
Place: Bermuda
Credit: 25 hours Category 1 AMA
Fee: $495
Info: Jacqueline D. Wright, Box 3808, Duke University Medical Center, Durham 27710. 919/681-2711

November 13
Divorce, Child Custody and the Family
Place: Johnsoo City, TN
Info: Sue Hutchinson, Quillen-Dishner College of Medicine, Johnson City, TN. 615/928-6426, ext. 204

November 14-17
Williamsburg Symposium on Perinatal Care
Place: Williamsburg
Credit: 12 hours Category I
Fee: $200
Info: Mary Valand, Box 7224, ECU School of Medicine, Greenville 27834. 919/758-5200

December 6-15
Review of Clinical Chemistry Seminar
Place: Snowmass, CO
Credit: 40 hours Category I
Fee: $315
Info: Mary Valand, Box 7224, ECU School of Medicine, Greenville 27834. 919/758-5200

Dx: recurrent herpes labialis



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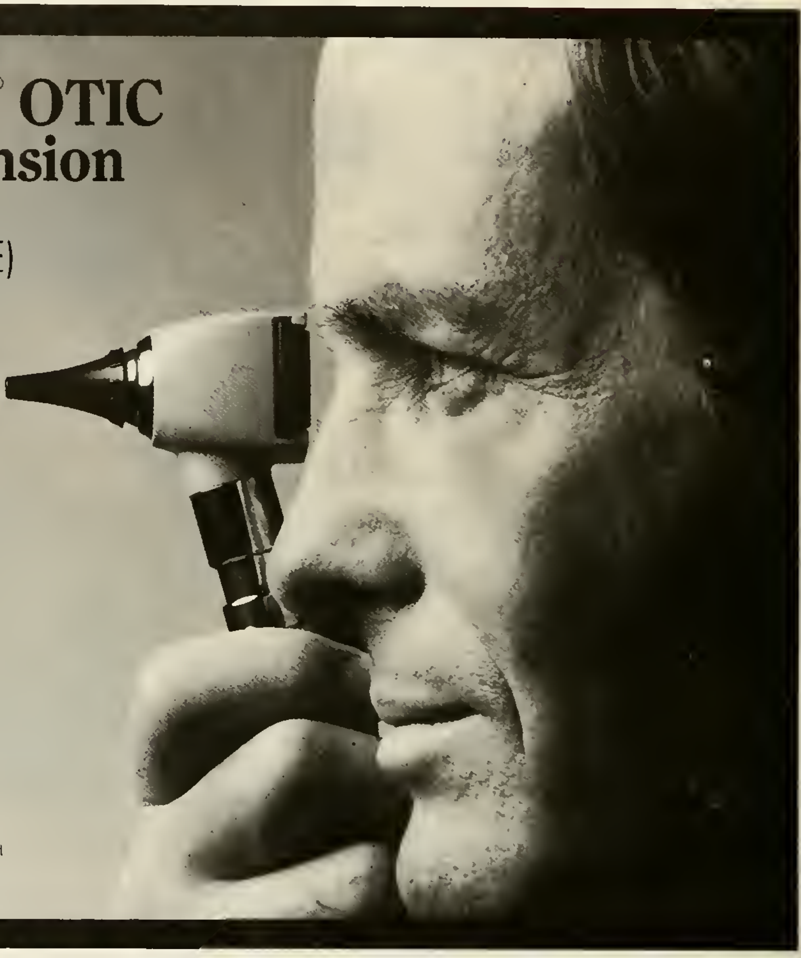

"In 159 of 163 clinically evaluated patients, the otic preparation (solution or suspension) was rated clinically effective, giving a clinical effectiveness for *acute diffuse external otitis* of *97.5%*."[1] (Emphasis added.)

EFFICACY RATES FOR OTIC SUSPENSION AND OTIC SOLUTION (COMBINED RESULTS FROM 4-CENTER STUDY)

	Clinical Efficacy
Suspension	
Total ears	93
Responders	91 (97.8%)
Solution	
Total ears	107
Responders	104 (97.2%)
Combined suspension and solution	
Total ears	200
Responders	195 (97.5%)

Adapted from Cassisi et al.[1]

REFERENCE:

1. Cassisi N, Cohn A, Davidson T, et al: Diffuse otitis externa: Clinical and microbiologic findings in the course of a multicenter study on a new otic solution. *Ann Otol Rhinol Laryngol* 86(suppl 39, pt 3):1-16, 1977.

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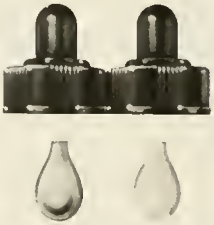

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The vehicle contains the inactive ingredients cupric sulfate, glycerin, hydrochloric acid, propylene glycol, water for injection and potassium metabisulfite (preservative) 0 1%.

Indications: For the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of the antibiotics.

Precautions: This drug should be used with care when the integrity of the tympanic membrane is in question because of the possibility of ototoxicity caused by neomycin

Adverse Reactions: Stinging and burning have been reported when this drug has gained access to the middle ear

Contraindications, Warnings, Precautions and Adverse Reactions Common to Both Products

Contraindications: These products are contraindicated in those individuals who have shown hypersensitivity to any of the components, and in herpes simplex, vaccinia and varicella

Warnings: As with other antibiotic preparations, prolonged treatment may result in overgrowth of nonsusceptible organisms and fungi If the infection is not improved after one week, cultures and susceptibility tests should be repeated to verify the identity of the organism and to determine whether therapy should be changed

When using neomycin-containing products to control secondary infection in the chronic dermatoses, such as chronic otitis externa, it should be borne in mind that the skin in these conditions is more liable than is normal skin to become sensitized to many substances, including neomycin The manifestation of sensitization to neomycin is usually a low grade reddening with swelling, dry scaling and itching; it may be manifest simply as a failure to heal During long-term use of neomycin-containing products, periodic examination for such signs is advisable and the patient should be told to discontinue the product if they are observed These symptoms regress quickly on withdrawing the medication Neomycin-containing applications should be avoided for that patient thereafter

Precautions: If sensitization or irritation occurs, medication should be discontinued promptly. Patients who prefer to warm the medication before using should be cautioned against heating the solution above body temperature, in order to avoid loss of potency

Treatment should not be continued for longer than ten days Allergic cross-reactions may occur which could prevent the use of any or all of the following antibiotics for the treatment of future infections kanamycin, paromomycin, streptomycin, and possibly gentamicin.

Adverse Reactions: Neomycin is a not uncommon cutaneous sensitizer There are articles in the current literature that indicate an increase in the prevalence of persons sensitive to neomycin

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Letters to the Editor

Anaphylaxis from Insect Stings

To the Editor:

There have been reports of unexplained deaths in healthy teenagers following exercise. I feel these deaths should be investigated by physicians in an attempt to find a common thread in the deaths. A complete history, examination, and autopsy should be performed when such a death occurs. All observers should be questioned.

The only unequivocal finding is a history of an insect sting. Tests for IgE antibodies for insect venom on postmortem blood can establish the fact that the dead person was in the 25 to 50% of persons who have the potential capacity to die from a sting. Of course, only a minute fraction with the potential for death will actually die from a sting.

Some patients upon autopsy will have laryngeal edema with obstruction, acute pulmonary edema, emphysema, and cerebral edema. These findings are non-specific.

Almost any system can be affected by insect sting reactions. I have had pathologists call me and give me their findings following a sting and ask me if this would occur after an insect sting. I replied in the affirmative. Sometimes the physician will not recognize the symptoms before death and the pathologist will not recognize the findings on the autopsy.

I would like to have any case of unexplained death sent to me, especially if it has been investigated and anaphylaxis is suspect.

Claude A. Frazier, M.D.
Doctors Park, Bldg. 4
Asheville 28801

To the Editor:

Many times it is difficult for a medical examiner or attending physician to determine if an individual has died from anaphylaxis due to insect stings, a food, or medication. In some cases the history is very clear and the event is witnessed; however, in many cases the evidence is not definitive. The usual differential diagnosis is anaphylaxis versus heart attack. Establishing the cause of death as anaphylaxis can be of significant benefit to the survivors, since most insurance companies consider anaphylaxis to be an accidental cause of death. In the case of insect sting allergy in particular and in reactions to many drugs and foods, anaphylaxis is mediated by antibodies of the IgE class, which are fixed to tissue mast cells. Some of the IgE antibodies are circulating in the serum, and it is easy to detect these antibodies by radioimmunoassay, even in postmortem blood. We have recently demonstrated this for eight cases of anaphylactic death from insect stings.[1] In collaboration with the Office of the Chief Medical Examiner we have been attempting to demonstrate the appropriate IgE antibodies in blood specimens from suspected anaphylactic deaths since 1979. We have, however, missed a number of cases where either no sample was obtained or the case was not flagged to arouse the suspicion of the Medical Examiner's office.

Examples of known causes of anaphylactic death include stings from bees, yellow jackets, hornets, paper wasps and imported fire ants, some drugs, e.g., penicillin, chymopapain, asparaginase, and other protein drugs, and foods, particularly peanut, nuts, egg, fish, shellfish, milk, etc. Insect bites almost never cause systemic anaphylaxis, the only exception being reduviid bugs of the genus *Triatoma*. Remember that bites are not stings. Bites come from the front end of the organism while stings originate from the rear. Reactions to intravenous contrast media, local anesthetics, aspirin, sulfa drugs, foods like strawberries and wine, and food additives like metabisulfite and tartrazine are not mediated by IgE antibodies and cannot at present be detected by *in vitro* tests.

In cases of suspected anaphylactic death we will be happy to test blood or serum specimens to determine if the deceased was sensitive to the suspected allergen. There is no charge for this service. We cannot provide this service for living patients without a fee. The radioimmunoassay for specific IgE antibodies can only demonstrate that the patient fulfilled a necessary condition for anaphylactic death and does not prove unequivocally that anaphylaxis was the cause of death. The incidence of IgE antibodies against some allergens like stinging insect venoms runs as high as 50% in some segments of the population. IgE antibodies against foods and drugs are much less common and a positive finding can be much more significant in these cases. In our experience every witnessed anaphylactic death from insect stings has shown the presence of the appropriate IgE antibodies.

Specimens for analysis should be accompanied by a short history or copy of the medical examiner's report. They should be sent via first class mail to me.

Donald R. Hoffman, Ph.D.
P. O. Box 3294
Greenville, NC 27836-3294
Phone: 919/757-2816

Reference

1. Hoffman DR, Wood CL, Hudson P: Demonstration of IgE and IgG antibodies against venoms in the blood of victims of fatal sting anaphylaxis. J Allergy Clin Immunol 1983;71:193-196.

More on Words of Wisdom

To the Editor:

It was very kind of Dr. David Silber to refer in his letter in the July issue of the NCMJ (45:325-326, 1984) to my "Words of Wisdom" as a "jewel." He is entirely correct about the dynamics of their crystallization. My conclusions *were* the result of "vast experience over substantial time in an atmosphere of institutional heat and pressure."

There is a history and a cast of characters behind each of my admonitions. This is not the time or place to go into detail, but an essay could be written about each. I would not dare publish many of the details in the NCMJ for at least a decade, some not in my lifetime, because I do not wish to defend myself against, even unwarranted, charges of libel. Dr. Silber may have suspected that admonitions 8-10 crystallized during a period when I was having an existential experience with our system of justice. If so, he was correct; and the period lasted for seven years. Never again!

I differ with Dr. Silber at only one point. He is very pessimistic where I am more optimistic about the value of education. I have lived long enough to observe that behavior *can* be modified if educational pressure is consistently applied over a sufficiently long period of time. It seems to me that this is the important historical truth that our species has documented since it invented language some millenia ago.

John B. Graham, M.D.
UNC School of Medicine
Chapel Hill 27514

Diabetes Day

To the Editor:

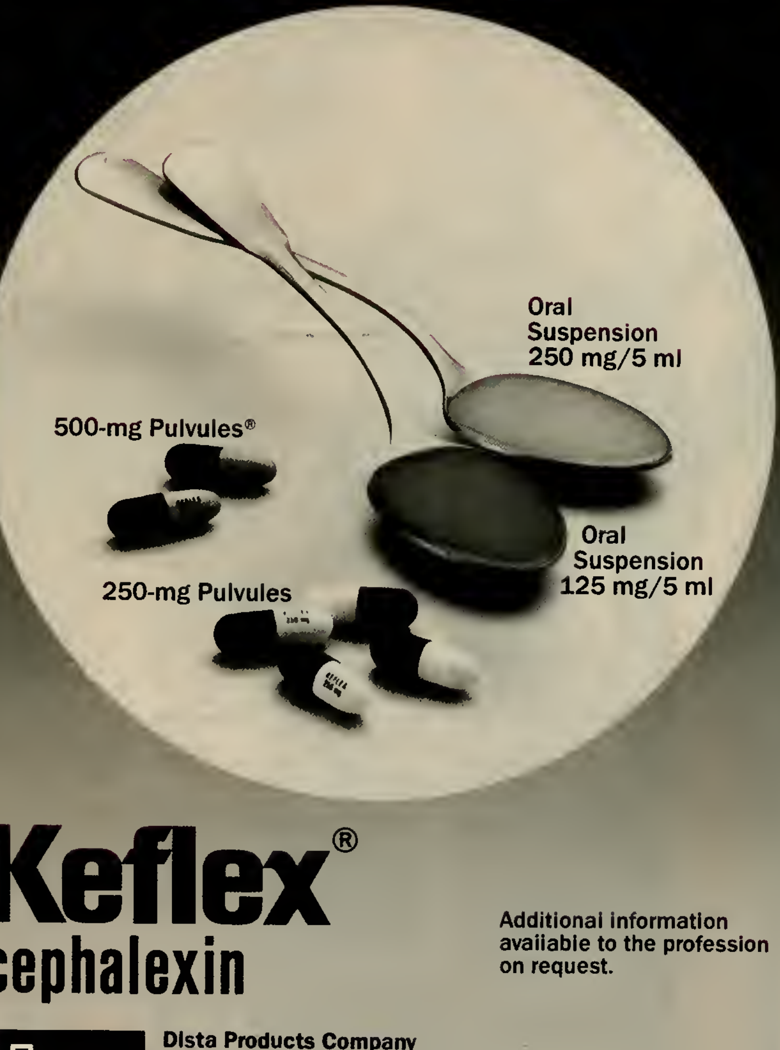
Insulin-dependent diabetes is a chronic illness which affects several thousand children and adolescents in North Carolina and neighboring states. In the last several years there have been revolutionary changes in the approach to treating this illness and there is great hope that the future is considerably brighter than in years past.

In order to provide information about the latest recommendations for management of insulin-dependent diabetes, the Division of Pediatric Endocrinology at Duke University and the North Carolina Affiliate of the American Diabetes Association are sponsoring Duke Diabetes Day on October 27, 1984. This program is designed for adolescents and children with diabetes, their families and friends, and the health care professionals who are involved in their care. Dr. Luther Travis will be the guest speaker and will address important issues in diabetic management and research. Information will be available about the new insulins and syringes. Pumps and instruments for home glucose monitoring will be displayed. Experts will answer questions about nutrition, control of blood sugar and importance of exercise. In addition, there will be activities for the whole family including games and prizes.

Duke Diabetes Day is designed to provide an opportunity to get to know one another. There is no charge. We would like physicians who care for children with insulin-dependent diabetes to notify their patients about Duke Diabetes Day and to join us on October 27. For more information, please contact Dr. Nancy Friedman, Duke University Medical Center, Box 3080, Durham 27710.

Nancy Friedman, M.D.
Associate in Pediatrics
Duke University

Easy To Take



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Multiple sclerosis destroys the myelin covering that surrounds nerve fibers in the brain and spinal cord. Messages to and from the brain get lost as they travel through the damaged areas. So your eyes, arms, legs don't do what you want them to do.

MS can be mild. Or it can be severe. Once you've got it, you've got it for life. Most days, Nancy Ray can get around with a walker. With a lot of time and effort, she can even prepare meals for her family. Some people with MS aren't that fortunate.

The National Multiple Sclerosis Society is helping people with MS live with MS. And funding research for a cure, all over the world. We can do it, but only with your help.

Please give generously. It's tough enough to be a mother without MS.

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Use the *Journal* to advertise for sale or wanted items of goods or service as well as professional or community notices. Rates: $25 first 25 words or less for non-members, $15 first 25 words or less for members, 25¢ each additional word. Write the *North Carolina Medical Journal*, P.O. Box 3910, Duke University Medical Center, Durham, NC 27710.

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References: 1. Kales J *et al*: *Clin Pharmacol Ther* *12*:691-697, Jul-Aug 1971. **2.** Kales A *et al*: *Clin Pharmacol Ther 18*:356-363, Sep 1975. **3.** Kales A *et al*: *Clin Pharmacol Ther 19*:576-583, May 1976. **4.** Kales A *et al*: *Clin Pharmacol Ther 32*:781-788, Dec 1982. **5.** Frost JD Jr, DeLucchi MR: *J Am Geriatr Soc 27*:541-546, Dec 1979. **6.** Kales A, Kales JD: *J Clin Pharmacol* 3:140-150, Apr 1983. **7.** Greenblatt DJ, Allen MD, Shader RI: *Clin Pharmacol Ther 21*:355-361, Mar 1977. **8.** Zimmerman AM: *Curr Ther Res 13*:18-22, Jan 1971. **9.** Amrein R *et al*: *Drugs Exp Clin Res 9*(1):85-99, 1983. **10.** Monti JM: *Methods Find Exp Clin Pharmacol* 3:303-326, May 1981. **11.** Greenblatt DJ *et al*: *Sleep* 5(Suppl 1):S18-S27, 1982. **12.** Kales A *et al*: *Pharmacology 26*:121-137, 1983

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The Official Journal of the NORTH CAROLINA MEDICAL SOCIETY October 1984, Volume 45, No. 10

New Hanover Memorial Hospital

Emile E. Werk, Jr., M.D. has gathered and edited ten articles in this issue of the *Journal* from New Hanover Memorial Hospital in Wilmington.

Walter Reece Berryhill
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Talking About Retirement Plans
Walter R. Rogers, Jr. and Jennifer M. Dibble, page 665

"Tips" on Clubbing and Arthritis
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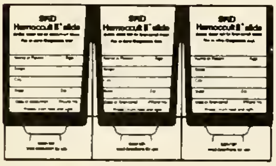

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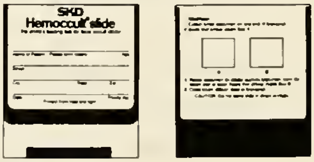

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Responders	195 (97.5%)

Adapted from Cassisi et al.[1]

REFERENCE:

1. Cassisi N, Cohn A, Davidson T, et al: Diffuse otitis externa: Clinical and microbiologic findings in the course of a multicenter study on a new otic solution. *Ann Otol Rhinol Laryngol* 86(suppl 39, pt 3):1-16, 1977.

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Precautions: If sensitization or irritation occurs, medication should be discontinued promptly. Patients who prefer to warm the medication before using should be cautioned against heating the solution above body temperature, in order to avoid loss of potency

Treatment should not be continued for longer than ten days. Allergic cross-reactions may occur which could prevent the use of any or all of the following antibiotics for the treatment of future infections: kanamycin, paromomycin, streptomycin, and possibly gentamicin

Adverse Reactions: Neomycin is a not uncommon cutaneous sensitizer. There are articles in the current literature that indicate an increase in the prevalence of persons sensitive to neomycin

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SPECIAL ARTICLE

Walter Reece Berryhill: Physician, Medical Educator, and Innovator

William B. Blythe, M.D.

WALTER REECE BERRYHILL was born on October 14, 1900, in his father's home, then located on a site that later became a runway for Charlotte's Douglas Airport. He attended school at the old Dixie High School in Charlotte where he became thoroughly grounded in, among other things, Greek. He at first planned to go to Davidson College but later changed his mind in favor of the University of North Carolina after visiting Chapel Hill as a member of his high school's debating team.

Descended from a long line of Scotch-Irish Presbyterians, noted for their strong sense of duty and decided Calvinistic tendencies, it is not surprising that he started out to be a Presbyterian minister. For those of us who knew him, it is also not surprising that when he did not become a minister, he became a zealous proponent and staunch defender of his other religion — the University of North Carolina and its medical school. For Dr. Berryhill, there was no better job or higher calling than the deanship of the University of North Carolina School of Medicine.

Together with my father, he came to Chapel Hill as a freshman in the Fall of 1917, a member of the famous class of '21 which supplied the state and nation with leaders in many fields. Three of Dr. Berryhill's life-long characteristics became clear during his undergraduate days: his intelligence, his high quality as a leader, and his ability to stimulate in others a sense of loyalty to him, the result of his loyalty to his colleagues. He was elected to Phi Beta Kappa; won the Eben Alexander prize in Greek; was president of the Student Council and of the senior class; and was an Assistant Editor of the *Tar Heel*, the student newspaper.

The 1921 *Yackety Yack* says this about him, "We want to remember you not only as Berryhill, Phi Beta Kappa, President of '21 and the rest, but as Reece, who could pass a pleasant and jovial smile, whose laugh was free, whose heart was ours, and (one) of whose leadership we were proud."

Some time during his college years, Dr. Berryhill decided that he could be of more service to people as a physician than as a minister. He changed his courses accordingly, but had to teach public school for two years after graduating to repay an obligation to the state from which he had received financial support. The obligation was discharged by teaching in the Big Springs School of Mecklenburg County the first year and in a private academy in Charlotte run by Major Baird the second year. Here he established friendships with people who were later to be very helpful when he became dean of the medical school in Chapel Hill.

Dr. Berryhill returned to Chapel Hill in 1923, spent two years in the medical school and, as was the custom with the top students, transferred to the Harvard Medical School from which he was graduated in 1927. He spent two years as a house officer on the Harvard Medical Service of the Boston City Hospital, then entered private practice and spent about six months in Belmont, North Carolina with a Dr. Pressly. While practicing in Belmont, he was asked by Dr. Isaac Manning, then Dean and Professor of Physiology, to come to Chapel Hill to teach the course in physiology because of Doctor Manning's illness. Despite protestations of an inability to teach physiology, he returned to Chapel Hill for about six months in 1929-1930 as an Associate Professor of Physiology.

A cousin of Dr. Berryhill's and a fellow Mecklenburger, Dr. Joseph Wearn, became Chairman of the Department of Medicine at Western Reserve School of Medicine in 1929. At his invitation, Dr. Berryhill moved to Cleveland to become his first Chief Resident.

Several months after arriving in Cleveland, Dr. Berryhill made the most important trip of his life — to become married to Miss Norma Connell of Warrenton, North Carolina. They had met some ten years earlier while she was a student at Peace College, and their friendship flourished when they were students together in Chapel Hill from 1923 to 1925.

They were married in Warrenton on August 2, 1930, forming a partnership that was undoubtedly most important in the future development of the four-year medical school in Chapel Hill. Only those who know Mrs. Berryhill well know of her importance in the partnership. Her modesty, her sense of humor, and her devotion to Dr. Berryhill and the University all serve to belie the multifaceted critical role that was hers.

Return to Chapel Hill
The Student Health Service

Some time in 1933, Dr. Berryhill received a letter from Dr. Frank Graham, President of the University of North Carolina, requesting that he return to Chapel Hill to become head of the Student Infirmary, Dr. Abernathy having died suddenly. He accepted the offer and stayed in Chapel Hill for the rest of his life. The title of his first job was Director of Student Health Services and Physician-in-Chief, University Infirmary. One of his first acts was to recruit Dr.

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Edward Hedgpeth as his Associate Director. Dr. Hedgpeth succeeded him as Director in 1941 and served the University for another quarter century. Dr. Berryhill was also an Assistant Professor of Medicine which meant in those days that he taught the second-year course in physical diagnosis.

In 1937, Dr. William deB. MacNider became Dean of the Medical School succeeding Dr. Charles Mangum. One of Dr. MacNider's conditions was that he be relieved of routine administration. To this end he recruited Dr. Berryhill as Assistant Dean in charge of student affairs with responsibility for admissions, guidance and counseling of students, and the transferring of students to the four-year schools. These duties were in addition to those of directing the clinical courses offered in the second year and running the Student Health Service.

Dr. MacNider never warmed to the deanship. His primary interests were research and teaching, and attending meetings elsewhere. The problems of University administration interfered with these interests, so he resigned as dean in 1940. Dean Robert House and President Frank Graham asked Dr. Berryhill to act as dean during the year 1940-1941, while a committee sought a replacement for Dr. MacNider.

Uppermost in the deliberations of the committee was the future of two-year medical schools. They concluded that such schools were insecure in the long run and that the University of North Carolina should begin planning for expansion to a four-year curriculum. Having reached this conclusion, the committee recommended Dr. Berryhill as the best person to accomplish this goal.

Becoming Dean

After initially declining the position, Dr. Berryhill agreed to assume the deanship for a period of five years, a length of time that he felt was reasonable for determining the real commitment of the university toward expanding the school. Dr. Berryhill later wrote that the decision was made only after he had received a firm commitment from the administration that a primary goal of the university was to expand the medical school when adequate financing became available, and that it would seek the funds required from the state and from private sources. The administration further agreed to provide immediately an increased budget to strengthen the basic science departments of the two-year school and to improve the teaching in the introductory clinical courses of the second year.

A quote from Dr. Berryhill illustrates his modesty and his loyalty to his teachers and to the University: "Even with these commitments on the part of the administration, it should be stated that the determining factor in the acting dean's decision to accept this responsibility — which he did not wish and which he was ill prepared to discharge — was the insistence of Dr. Isaac Manning, Sr. that this had to be his decision if the future of the school was to be made secure by its expansion to a four-year status."

The decision had hardly been made when the U.S. entered World War II and faced more immediate problems. Within three months after he became dean — shortly after January 1942 — the school announced the adoption of an accelerated program to enable students to complete the work of the first two years in eighteen months, i.e., vacations disappeared. This necessitated two changes which had to be effected almost overnight: (1) changing the schedule so that it correlated with those of the four-year schools, and (2) introducing new subject matter pertinent to military medicine. All of this was accomplished in less than six months so that by June 1942 the school began admitting students every nine months, a practice which continued until war's end. This remarkable feat, accomplished by all the U.S. medical schools, was done in the face of a faculty manpower shortage and the near impossibility of recruiting faculty members in wartime, especially to a two-year school. Dr. Berryhill wrote of this time with characteristic understatement, "all of this was done without too much hardship on either faculty or students. Both accepted the necessary adjustments, the longer hours and the added strain in a fine fashion and attempted to make the most of the situation." It should be pointed out that both students and faculty thoroughly enjoyed the long vacation between April and September 1946 when it finally arrived.

Figure 1. *The newly appointed Dean, 1940s.*

The Campaign for Expansion

Despite the trying and taxing times, Dr. Berryhill began to develop and execute the strategy that eventually led to a four-year school. Concurrently, he organized what he referred to as "discussions" among influential faculty members and university administrators, influential medical alumni, members of the Board of Trustees of the university, and leaders of the State Medical Society. He worked away steadily on this project during the war years.

The result of these "discussions" was a committee appointed by President Frank Graham and headed by Dr. Paul McCain, the head of the Tuberculosis Sanitorium System. The committee's charge was to develop a proposal which could be discussed with Governor Broughton and, if he concurred in the proposal, could be presented to the Board of Trustees of the university for their consideration. (In those days the Governor was chairman of the Board of Trustees.) The essence of the McCain committee's proposal was that there should be state support for expansion of the medical school to four years and for the construction of hospitals in rural areas and in areas where hospital facilities were inadequate in size or already too outmoded to meet the demands for adequate medical care.

Governor Broughton enthusiastically endorsed the proposal of the McCain committee and presented it to the Board of Trustees of the Consolidated University. The trustees unanimously approved the proposal — now Governor Broughton's proposal — and authorized the appointment of a state commission "to study all aspects involved" and charged it with submitting recommendations for implementing the outlined goals to the General Assembly in 1945. Governor Broughton appointed Mr. Clarence Poe, publisher of the *Progressive Farmer*, Chairman of the commission which became known as the Hospital and Medical Care Commission (HMCC).

The HMCC spent almost eight months in study. Early in October 1944 it adopted a report for submission to Governor Broughton and appealed to the people of the state for their support in its implementation. In brief, the report delineated in well-documented fashion the need for more doctors, more hospitals, and more voluntary insurance plans to cover hospital and medical care costs.

In November 1944 Governor Broughton arranged to have the recommendations of the HMCC presented to the Advisory Budget Commission in preparation for action by the 1945 General Assembly. The Advisory Budget Commission took the position that since this was an entirely new undertaking of great importance to the people of North Carolina and one which would result in the commitment of a large amount of money, the General Assembly should decide about whether to implement the recommendations.

The General Assembly of 1945 formally established the North Carolina Medical Care Commission (NCMCC) and appropriated funds for loans to students in the medical schools of the state who would agree to practice in rural areas, and authorized the trustees of the university to expand the medical school to four years. However, an amendment was appended to the legislation which requested further study by a group of experts from outside the state to determine the best location for the four-year school before the authorization could be implemented. This resulted in the appointment by the Medical Care Commission of a National Committee headed by Dr. W. T. Sanger, president of the Medical College of Virginia, to study the question of the best location for the proposed four-year school and hospital. Furthermore, the legislature's charge was expanded by members of the NCMCC who opposed expansion of the school to include a study of the *need* for an expanded school.

The majority of the Sanger Committee recommended that the School of Medicine of the University be expanded and that it be located in Chapel Hill. Furthermore, the committee recommended that the functions of the medical school be broadened, and emphasized the importance of regionalization in the delivery of medical care in the state.

Dr. Berryhill wrote of this time 1945-1947, "While the majority of the commission approved the recommendation and worked steadfastly for the next two years to bring about favorable action by the 1945 and 1947 General Assemblies, there was far from unanimity of agreement among its members on the two major issues — the use of state funds for hospital construction in communities deficient in hospital beds and the expansion of the university school of medicine with the construction of a university hospital at Chapel Hill."

The lines were quickly drawn, and a battle began which raged throughout the state with considerable fervor — even ferocity. Its effects were evident for some years following the action of the 1945 and 1947 General Assemblies, which finally passed legislation which implemented essentially all of the recommendations of the Sanger Committee. (The battle over establishment of the State's second medical school at East Carolina was pale by comparison.)

Initially, some members of the medical profession, as well as civic leaders, felt that state funds to assist in the construction of community hospitals meant state control and therefore constituted socialized medicine! Another and rather powerful group was concerned about the cost of constructing community hospitals and especially the cost of building and operating a four-year medical school and teaching hospital within the university. Enthusiasm was also lacking among many elements of the Arts and Sciences faculty at Chapel Hill. The location of an expanded school once again became the focus of debate, as it had frequently been over the past fifty years.

Some felt that North Carolina did not need three medical schools, and that the two privately endowed schools, Duke and Wake Forest, could supply the needed doctors and health personnel without a large expenditure of tax funds. Representatives of these schools — faculty, alumni, and others — urged the appropriation of state funds for physical enlargement and increased operating budgets at the private institutions rather than state appropriations for the expansion of the University of North Carolina two-year school.

Finally, in March 1947, the legislative Joint Appropriation Committee, after hearing long and impassioned arguments from both sides, approved the permanent improvements appropriation for the university, which included the funds requested for expansion of the medical school and construction of a hospital to be located in Chapel Hill. At Governor Cherry's suggestion, however, only planning funds were to be appropriated until the post-war inflation had subsided ("when we can get a dollar's worth of construction for a dollar"). Observing the continuing inflation, the subsequent Legislature released the funds.

Meanwhile, another obstacle appeared. A group from Greensboro offered the potential Moses Cone Hospital as the primary university hospital together with a substantial endowment. The idea was that the medical school move to Greensboro and become intellectually based on the

Woman's College of the University. After much discussion, this offer was declined by the university, and plans for the development at Chapel Hill moved swiftly onward.

Expansion of the Medical School

The period of 1948-1954, marked at the beginning by development of plans for the four-year school and at the end by graduation of the first four-year class, was both exciting and trying for Dr. Berryhill. The two most important undertakings of this time were the actual physical expansion of the Medical School, including the building of the North Carolina Memorial Hospital and recruitment of faculty and staff necessary for operating the clinical departments and the hospital.

Despite unforeseen difficulties, including optimistic underestimates of cost and continuing inflation, which initially resulted in insufficient funds for physical expansion, the necessary money ($5,000,000) was finally obtained and construction began in November 1949, the hospital opening in September 1952.

Dr. Berryhill's ideas about the type of faculty needed for the four-year school were undoubtedly a major factor in the success that the medical school has achieved. This is what he wrote later about the criteria used in selecting chairmen for the clinical departments: "In selecting the chairmen of the clinical departments in 1951-1952, certain criteria were insisted upon — criteria which by 1969 might have been, in all too many instances, considered outdated in many schools of medicine, including perhaps this one. Those criteria were: (1) excellence as a clinician and active participation in the care of patients; (2) superior teaching ability and devotion to this responsibility with respect to both undergraduate medical students and to interns, residents, and fellows; (3) competence in clinical research; (4) evidence of a desire and motivation to work with others for the improvement of medical education at all levels in the medical school; and (5) possession of a sense of responsibility to the university and the state of North Carolina."

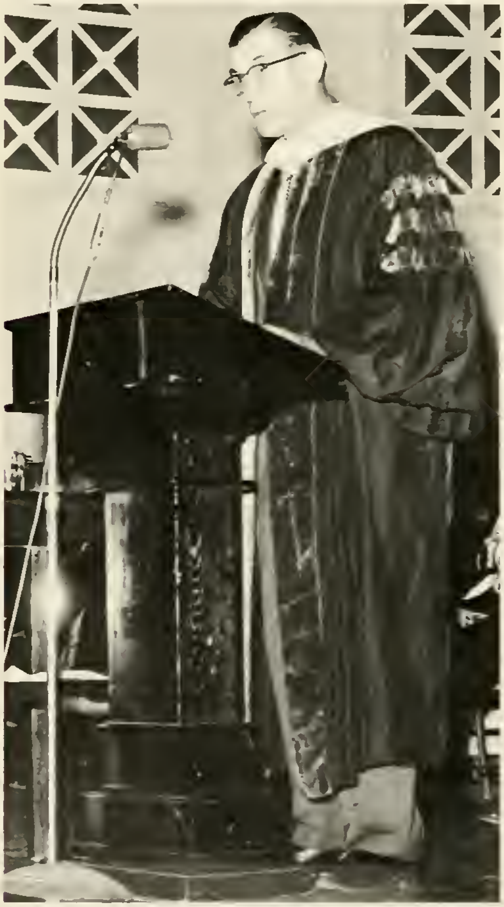

Figure 2. *Addressing the first graduating class of the four-year medical school, 1954.*

In spite of many difficulties, all four medical school classes were in residence at Chapel Hill in 1954, for the first time in the history of medical education at Chapel Hill, and for the first time since 1910, the university awarded the Doctor of Medicine degree. Graduation day marked the achievement of what Dr. Berryhill considered his major life goal.

He continued as dean of the medical school for another decade, a time that saw the school develop into one of major national prominence, although not without turbulence. John Graham, who participated in many of these events, describes them elsewhere.

The Third Career

Dr. Berryhill resigned the deanship in 1964, and after a year's leave of absence during which time he was a Commonwealth Fund Traveling Fellow, he began a third successful career which was also dedicated to the health of the people of North Carolina. He became the first director of a newly-formed division of the medical school, The Division of Education and Research in Community Medical Care. As its title suggests, this division's major objective was to improve the mutually beneficial relationships between the medical school and the local communities in the state. Specifically, Dr. Berryhill considered that the division should be concerned with improving the methods of continuing education for physicians in their own hospitals; and in developing joint university-community hospital teaching services in various types of clinics and hospitals. The objective was to provide a better balance in the educational experience of undergraduate medical students, interns, and residents, as well as the medical faculty, by providing an opportunity for all to become more knowledgeable about problems of medical care in the community. He was also interested in initiating studies and consulting about methods by which medical care could be more effectively delivered to the communities in the future.

The work of this division set the stage for the Area Health Education Centers program in the state, a program that is now recognized as one of the most effective and outstanding of these programs in the nation. David Citron describes the AHEC activities in his contribution.

Dr. Berryhill officially retired from the University in 1973, but remained active in the affairs of the medical school until his death on January 1, 1979. In fact, until shortly before he died, he was intimately involved in the planning for the centennial celebration of the School in February, 1979.

I shall conclude this account by quoting what I wrote about Dr. Berryhill after his death in 1979: "These are some of his accomplishments, but the man was much more than these. For those who knew him, he was the embodiment of dedication, integrity, loyalty, and selflessness — qualities which assumed saintly qualities when one was in accord with him, and which might have been thought of as inordinate Scotch-Irish contrariness in disputatious matters.

"But whether or not all might not have agreed with him all the time on specific issues, all ardently agree that Doctor Berryhill was totally dedicated to his beloved university and medical school — as well as to his state — and that they are all nobler because of him.

"As is the case with many great men, he did not stand alone. Throughout his professional life, he had the help of an equally dedicated, perceptive, modest person — Mrs. Berryhill. Together — and synergistically — they made the four-year medical school at Chapel Hill."

A Personal Note

The first time that I recollect hearing of Dr. Berryhill was in early 1944 when I was 15 years old and a senior in high school. I remember the occasion vividly. My father and I were having a discussion in an upstairs bedroom about what I might like to do with my life. There was much talk about going to the U.S. Naval Academy or of becoming some sort of forest ranger, two romanticisms that were appealing to me then.

Somehow, neither of these notions — as well as some others — were entirely satisfying either to me or to my father! I finally decided that a career in medicine might be the answer. It seemed to offer the possibility of combining my interest in natural science with an ill-formed, but nevertheless compelling, adolescent altruism.

The discussion ended promptly. My father said, "You have made a fine choice. Now, we need to write Reece Berryhill — he's now Dean of the Medical School at Chapel Hill — and find out what you should do to prepare yourself." My father wrote to Dr. Berryhill and sometime later a letter arrived from him. As I reflect on it, the essence of the letter was the essence of Dr. Berryhill. First, he expressed delight in hearing from my father, a friend since their Chapel Hill days; next, he expressed delight in hearing that my father had a son who was interested in studying medicine; he then prescribed in general terms what I should do to get ready for medical school; and he ended up by describing briefly, and in somber terms, the nature of the problems of the Medical School and the University and what had to be done to overcome them.

Thus, he had expressed genuine friendship and loyalty to an old friend, offered candid, straightforward advice to a student, and outlined the problems — not the accomplishments — of the Medical School and University to a citizen of the state.

There is no telling how many letters like this that he wrote.

It was not until his last years that I was able to spend much time talking to Dr. Berryhill. Then I would go to his office frequently and seek his advice and opinion on many things. He never changed. He continued to be interested in medical students and prospective medical students; his love for the Medical School and University were never dimmed and distorted by an old man's bitterness (although he still had sharp words for some happenings that he did not like); he never spoke of his accomplishments; and he continued to give me candid, straightforward advice. He was a remarkable man!

SPECIAL ARTICLE

Walter Reece Berryhill: Dean of Medicine, 1941-1964

John B. Graham, M.D.

As Bill Blythe has pointed out, Dr. Berryhill was Dean of the Medical School at Chapel Hill for 23 eventful years and should be regarded as the architect of the four year school of medicine.[1] His charge had been to bring about the metamorphosis of a small, regional, two-year school of medicine into a comprehensive medical center. This was to be accomplished in a venerable state university with strong traditions, and with vested interests in the arts, humanities, and social sciences which would be greatly threatened by the change. There would probably be turmoil and strife, and it would be necessary both to maintain strong political support within the state and to recruit an outstanding faculty from the national pool. Accomplishing such goals would require a remarkable person. Walter Reece Berryhill proved to be the right person at the right time in the university's history. He accomplished his

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[1] I never addressed him other than as "Dr. Berryhill," and to me and many of my contemporaries he will always be THE DEAN.

monumental task, but it was not without travail as I shall recount.

I was a member of the faculty for 18 of the 23 years of Dr. Berryhill's deanship and worked on many of his projects. I never knew exactly how he viewed me, because we were very different in attitudes and temperament, but we shared a devotion to the institution. He seemed to turn to me when there was a particularly sticky problem which others shied away from. He must have known something about me which I didn't know about myself.

A Man of Character and Determination

Dr. Berryhill was large and imposing. He had a simple sense of humor and lacked a light side. Every conversation I ever had with him sooner or later became serious, usually coming around to our mutual concern with the less than satisfactory state of university affairs. Both of us had been reared as Presbyterians and had similar views about Original Sin as it affects all human, and especially university, activities. Our wives must have become very weary of hearing us discuss the venality and incompetence of our masters. The university was Dr. Berryhill's "religion," if by religion one means what Paul Tillich meant, "that which means more than anything else." He must have seen in me someone equally committed, because he repeatedly challenged me to take actions in the larger university arena which he could not take because of his position. (See "Revolt of 1956"; "Holman Committee") I usually rose to the bait, because, I suppose, it played to my suspicion that I was faint-hearted. He was very clever!

Dr. Berryhill possessed *gravitas* in full measure, a quality which automatically induces respect in others. One knew instinctively that he was completely serious and that levity had no place in a business discussion. This gave him a power with subordinates that I have seen duplicated in few others.[2] I once heard him say that he could judge a person's motives and quality by listening carefully to a conversation. At the time, I suspected that he used this as an excuse to hide the exercise of his prejudices, because there seemed to me to be insufficient data in conversation to reach a judgment. Now I realize that he was extraordinarily astute and usually reached correct judgments about people, although not entirely from conversation. He must have developed his interview technique empirically, because I never heard him quote an authority for the view that conversation provides a window on the mind. If his *gravitas* and impassivity had the same effect on others that they had on me, he must have obtained a great deal of information which interviewees had not initially intended to transmit.

A key feature of Reece Berryhill's leadership was his attitude toward "administration." He believed that it should be kept to a minimum and prevented from interfering with more important matters. The fewer people involved the better. He operated the School with a minimum of assistance: Mrs. Privette, then Miss Dunlap, and finally Miss Dunlap and her several assistants, never numbering more than a half-dozen. He made decisions with ease and without fuss. Philip Manire, a long-time medical faculty member and now Dean of the Graduate School, says that Dr. Berryhill not only disdained administration, he lost respect for anyone who aspired to an administrative career. He did not deign to train assistant deans, believing that administration consisted of the application of common sense and that any good person could do it. He tried to avoid long business and committee meetings and developed an effective technique. If one asked for an appointment, he often replied that he preferred to drop by one's office. This allowed him to break off a discussion whenever he wished by suddenly remembering another appointment.

Dr. Berryhill was a man of his word. If he made a commitment, he kept it. This meant that he had to consider a proposition carefully before agreeing to it. Although this required great mental energy, he did not procrastinate. He was a prodigious worker. As a leader, he knew that he could only point the way to others. It was their responsibility to do their own jobs as carefully as he did his. This style of leadership meant that he must know well and possess the confidence of those he was trying to lead. He accomplished this by using a variety of social mechanisms to meet and get to know his faculty. The Berryhills gave many parties and, with Southern gentility, always called when tragedy struck. I doubt that anyone who joined the faculty while he was Dean failed to receive at least one invitation to dinner. I recall how downcast he was when he realized that the faculty had become too large to be entertained all at once!

Mrs. Berryhill was equally concerned about the welfare of the families of new faculty members. She saw to it that their wives became informed about the affairs of the community, and became involved, if they wished, in the many worthwhile service committees. Such committee work is no longer as fashionable as it once was, but the present generation has apparently re-invented the wheel under the rubric "support groups," which accomplish the same ends. The Berryhills were a formidable pair and earned the devotion of the large group of newcomers to the school who arrived during the 1950s. This devotion stood Dr. Berryhill in good stead in the mid-1950s when there was an abortive attempt to unseat him, a misguided affair which led to the faculty "Revolt of 1956" about which more will be said later.

It has been my observation that the possession of strong emotions is characteristic of those who accomplish great things, and Dr. Berryhill is one of my examples. He kept his emotions in strong check, but they erupted occasionally. When this occurred, he was apt to make errors in judgment. He was strong enough, however, to reverse a bad decision without loss of face when he had cooled down. Mrs. Berryhill says that he could do this because "he knew who he was." I agreed. He was, in David Reisman's phrase, "inner directed." When he thought he was right, he didn't care what anyone else thought.

Preparation for the Deanship

I had not been conscious as a premedical student at Davidson that there *was* a medical school at UNC. Duke Medical School, then 8 years old, was new and attractive and I applied and was accepted. But my roots were deeply embedded at Chapel Hill, and my family and friends urged and finally convinced me to switch schools. I was assured, correctly, that transfer would be a simple matter, and went to Chapel Hill in July 1938 to investigate. I was directed to the Student Health Service, then in Abernethy Hall, where I met a tall, serious, white-coated doctor, the medical school's Assistant Dean, who asked several direct questions.

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[2] Dr. Charles Burnett, our first Professor of Medicine, also had this quality. Dr. Burnett's subordinates often referred to him — beyond his hearing — as "Steely Blue Eyes."

"Why do you want to transfer from Duke?" "I think I would be happier here."
"Are you a good student?" "I have a better than B average in my sciences, and made straight A's my senior year."
"Do you have your transcript with you?" "No, but I can get one."
"Don't bother, I'll do it. You'll hear from me in a few days."

The interview lasted less than ten minutes, and a week later I received a telegram from Dr. Berryhill informing me that I had been admitted. I suppose a committee might have met, but it is more likely that he had made the decision himself. It would have been in character for him to have spared others the trouble of involvement in such a trivial matter.

As a student, I had few contacts with Dr. Berryhill, who was both Director of the Student Health Service and Assistant Dean of the Medical School. My recollection is that he spent mornings at the Infirmary holding sick call, and afternoons running the Medical School.[3] I thought that I was, perhaps, unique in seeing so little of him. I learned years later that my classmates had had similar relationships with him. As a student I regarded him as austere and aloof. Now I view him as having been extremely busy, but concerned about his students and responsive to their needs. He simply lacked small talk and was not effusive. Three contacts with him during my student days 45 years ago are still bright in my memory.

Within a few weeks of matriculation in 1938 my class of 35 — medical students were not married in those days — were entertained by the Berryhills at their home on West Franklin Street. It was a bright Sunday afternoon in October. Their large home was on a slight elevation above what is now Fowler's Foodstore, and the beautifully landscaped lot sloped down to a creek over which a service station and Fowler's have been built since World War II. The grounds were spacious, the hosts were gracious, and the food was delicious. It was a delightful occasion.

Dr. Berryhill's course in Physical Diagnosis was unusual in one particular. He was a large man and had very thick fingers. When he percussed the boundaries of the heart for a group of students, the sounds changed so dramatically that one could almost see the boundaries. How I envied this talent of his!

My third memory is of an event on my last day as a student in Chapel Hill. It illustrates Dr. Berryhill's drive for continued improvement and his willingness to seek advice in unusual places. I had completed my examinations and was packing to go home. Suddenly I was informed that Dr. Berryhill wished to see me immediately. My heart almost stopped. What had I done? I ran up the hill from Whitehead Dormitory to MacNider and entered his office. He was seated behind his desk in front of the window, the inevitable cigarette in his hand. I examined him quickly for signs of anger, but he seemed to be his usual taciturn self. He proceeded systematicaly to extract my views of the adequacy of the medical school curriculum, and my opinion of the various courses and instructors. I was very reluctant in my youth to express my opinions, but since he had asked for them, he got them. Later I was very pleased to learn that he had taken many of my suggestions seriously and had acted upon them.

This habit of seeking advice from a wide range of advisors must have been a regular practice. When I returned from World War II — still in uniform and not yet on the university's payroll — the now Dean asked me to review and express my opinions about the curricula vitae of three men who had been short-listed for the Chair of Pathology, one of whom would become my Boss. I was baffled about how to judge them, but one thing is clear. Even then he was selecting chairmen with great care. Two of the three men were Ken Brinkhous and Tom Kinney, both of whom became national and international figures in Pathology. He used the same standards later in selecting the clinical chairmen.

Dr. Berryhill hoped that every student who transferred elsewhere would do so without "culture shock." This was difficult because each of the about thirty schools to which we transferred had had a generally similar but slightly different set of courses in the second year. The variations were dutifully reported to him by the transferees and, because of his concern, he tried to introduce them into Carolina's curriculum. I suppose there were advantages for subsequent transferees, but the second year of the old two-year curriculum became saturated with courses in Public Health, Obstetrics, Pediatrics, Dog Surgery, etc. When the clinical faculty arrived in the early 1950s, it found a curriculum already geared to excessive clinical teaching in the second year, a condition from which it has never recovered.

After leaving Chapel Hill for Cornell in 1940, I remained in touch with Dr. Berryhill and he helped me to get my residency. He offered me a job in 1944 as I was finishing at New York Hospital, because the pathologist at Watts Hospital had been drafted and the Pathology department was having to assume the management of Watts' laboratories. Drs. Bullitt and Holman badly needed help, but I felt that I had to serve in the Armed Forces. I was able to help them recruit John Miale, but I think all of us knew that I would be returning to Chapel Hill after the War, if I survived and there was a place for me.

The Deanship: Early Years

Except for a visit to Chapel Hill while I was recuperating from hepatitis in 1944, I did not see Dr. Berryhill between 1940 and 1946. During the war years he was largely occupied by the accelerated educational program and laying the groundwork for the campaign for the four-year school. My colleagues, Dr. Citron and Miss Dunlap, were present then, and we must depend on them for information about those days.

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[3] I have since learned that Dr. MacNider agreed to be designated Dean only if his duties were limited to participating in policy decisions and attending ceremonies.

I joined the university faculty as an instructor in the fall of 1946 at a time when appointment to an assistant professorship was automatic if one possessed a terminal degree, unless the degree happened to be an M.D. and its possessor a member of the medical faculty. Dr. Berryhill had been reared in the austere Harvard and Western Reserve traditions wherein one remained an instructor, often unmarried, until ready to become a department head or dean. When he hired Ted Blount, Lytt Gardner, John Riggsbee and me as instructors in 1946-47 at $300/month, I was still in uniform and on terminal leave. I was happy to have a job to help support my wife and child. The others were planning to practice medicine, but I was planning to teach. I was, therefore, assigned extra duty. In addition to teaching three quarters each year, I was also placed for 3 years on the overworked Admissions Committee which had the job of selecting 50 medical students each year from the huge pile of applications being submitted by returning veterans.

The fall of 1946 was very exciting. The Legislature, scheduled to convene in January 1947, was to receive and consider the recommendations of the Sanger Committee. This out-of-state body had recommended that the state convert the two-year medical school at Chapel Hill into a four-year school, establish a related university hospital, and start new schools of Dentistry and Nursing. Together with the existing schools of Pharmacy and Public Health, this would provide the state with a panoply of health science institutions. It was the four-year medical school over which blood was destined to be spilled, but the Sanger Committee also recommended the establishment of a statewide network of related hospitals based upon a central unit in Chapel Hill. Having just spent six years in New York and the Army, I cynically assumed that the concept of a statewide hospital network was merely campaign oratory whose purpose was to assure the acquisition of the four-year school. Time has proved me wrong. It was this recommendation which lies behind the establishment of the AHECs, which Dr. Berryhill was to bring into existence in the "fulness of time." He actually had three separate careers at Chapel Hill: Director of the Student Health Service, Dean of the Medical School, and originator of the AHECs. The one for which he is best known is the medical deanship, the task on which I served with him. But when he retired, he tackled the unfulfilled part of the Sanger report and established the hospital network. This development is described elsewhere by Dave Citron.

Bill Blythe has described the political campaign for converting the medical school into a four-year curriculum, a movement that had been underway for many years. Dr. Berryhill had worked very hard on the project, and it was successful. The Sanger report was approved by the 1947 legislature, and planning funds were appropriated. Building funds were provided in 1949, and the North Carolina Memorial Hospital — a memorial to the dead of both World Wars — opened in 1952.

While the hospital was being built, Dr. Berryhill spent most of his time recruiting the clinical faculty. His method was simple: recruit first class department chairmen and let

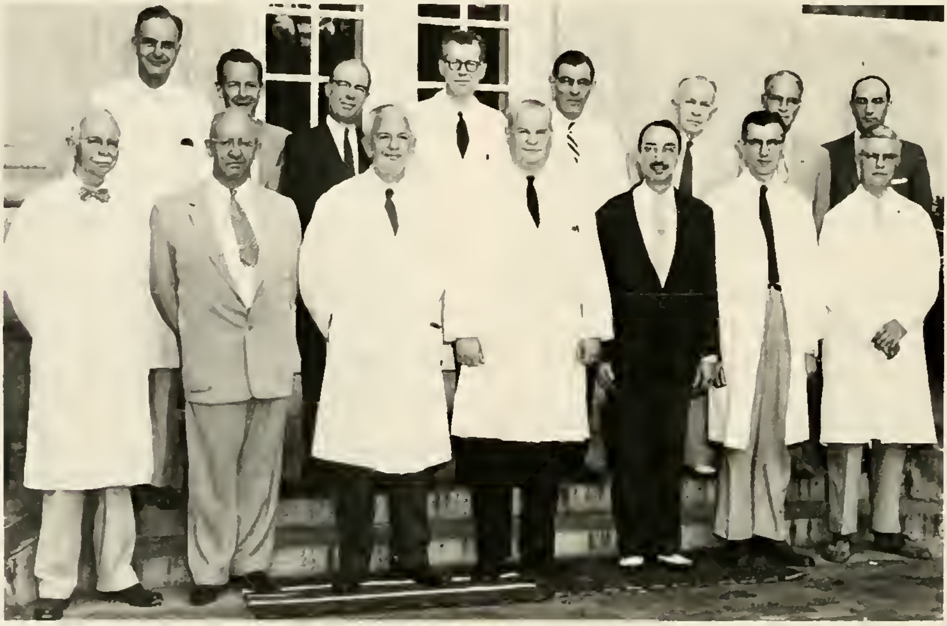

Figure 3. *The department heads, 1954.* Front row: *D. A. Macpherson (Bacteriology), James Andrews (Biochemistry), Nathan Womack (Surgery), Robert Ross (Obstetrics), William Richardson (Continuing Education), Kenneth Brinkhous (Pathology), George Ham (Psychiatry).* Back row: *Thomas Butler (Pharmacology), Charles Hooker (Anatomy) William Fleming (Preventive Medicine), Edward Curnen (Pediatrics), Reece Berryhill (Dean), W. C. George (Anatomy), Charles Burnett (Medicine), Robert Cadmus (Hospital Administration).*

them do the rest. He scoured the entire country for chairmen, taking full advantage of his contacts in the foundations, and in Boston and Cleveland. He was spectacularly successful. Duke's Dean Wilburt Davison, perhaps in a burst of hyperbole, is reported to have said that Berryhill had brought together the best group of clinical department heads since Welch had established the Hopkins with Osler, Halsted, McCallum, etc. Dean Davison may have exaggerated, but the achievement was real and has been lasting. Dr. Berryhill succeeded in a single stroke in changing a small but good, regional teaching institution into one that aspired to be a comprehensive medical center with national standards in teaching, research and patient care. But it was not all smooth sailing as we shall see. Dr. Berryhill made a negative decision in 1949 whose effects hampered him for the rest of his deanship.[4]

The Deanship: Later Years

The higher administration believed that an "Administrator" was required for the Division of Health Affairs, someone to oversee the health schools and the university hospital. The position was offered first to Dr. Berryhill. After consideration, he declined, arguing that organizing the medical school properly was as much as he could handle, besides he knew nothing about the methods and standards of the other disciplines.

In retrospect, this was probably a mistake. His two major contributions — the successful political campaign and the recruitment of the clinical chairmen — had been largely completed by 1950, and as time has shown, the job of Administrator of Health Affairs is largely ceremonial. He could probably have melded this position with the deanship and managed both, thereby avoiding the troubles to which his declination was to lead. I do not know that anyone considered linking the two positions, but since he was not interested, the administratorship of Health Affairs was offered to and accepted by a former student fifteen years his junior.[5]

The Administrator's experience had been in administering university hospitals rather than in practicing medicine and teaching medical students. He was very knowledgeable about and interested in medical care, but less so about the ordinary problems of medical education and medical research. On the other side, the clinical faculty was a vigorous, ambitious group of young doctors who were very interested in advancing their careers through teaching and research. The new organizational structures forced them into frustrating and wasteful inefficiencies. They had to deal with Dr. Berryhill on some matters and the administrator of the hospital on others, and the boundaries of responsibility between the two were very hazy. The conflicting goals and the strong personalities involved led to what I shall call the faculty "Revolt of 1956."

There were three issues: 1) Dr. Berryhill's suitability as Dean, 2) administrative control of the hospital, and 3) the status of the medical school within the Division of Health Affairs. By votes at a mass meeting, the medical faculty indicated its confidence in the Dean, requested that the university hospital be placed administratively within the School of Medicine, and indicated its unhappiness with the overall administrative structure. The resolutions led to a conference between a committee of faculty members and Chancellor House, Acting President Friday, Vice-President Carmichael, and Acting Dean of Law Aycock, who was destined to succeed Chancellor House. The faculty's request concerning the hospital was accepted, and Dr. Berryhill assumed responsibility for its operation. The issue of whether the School of Medicine was co-equal to the other schools of the Division or, because of its size and complexity, was entitled to special treatment, was not resolved until the Holman Committee's study of 1962-63[6] and the appearance of Chancellor Sharp, Aycock's successor.

Not all of the turbulence in the medical school in the mid 1950s was related to poor external relations. There was also a strong difference of opinion *within* the medical faculty about its own decision-making processes. This led to an episode in 1957 known at the time as "The Revolt of the Associate Professors," and Dean Berryhill supported the rebels!

It has been customary in European universities for each department to have a single PROFESSOR as head, or Geheimrat. This system was transplanted from Germany to Johns Hopkins and Chicago in the 19th century and became normative in American medical schools after the Flexner Report of 1912. The basic medical science departments at Chapel Hill were small before World War II, usually consisting of one older and one or two younger teachers. The elder was always a Professor and the younger teachers usually left for other jobs before reaching professorial age. Thus in 1950, it was natural to have only a single professor in each department of the medical school, although professorships were not limited in other departments of the university. The enlargement of the medical curriculum to four years and the need to teach dental and para-medical students led to much larger departments, some of which contained numerous Associate Professors. Dr. Berryhill had utilized the existing department heads, all professors, as advisors in enlarging the school. They had met regularly and had come to regard themselves as having an executive function. Several of them decided to try to impose the European professorial model on the medical faculty by the fiat of this quasi-Executive Committee. The Associate Professors, of whom I was one, were enraged and began agitating. We had been Dr. Berryhill's main support when he had been under fire the preceding year, while some of the department chairmen had not exerted themselves on his behalf. Dr. Berryhill opposed the coup, and the attempt failed. Following this, he proposed a constitutional assembly.

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[4] His other advisors and I must share the blame. He and I discussed his pending decision on a bus between Colorado Springs and Denver while returning from the 1949 AAMC meeting. I was not experienced enough at age 31 to advise him wisely.

[5] Christopher Fordham held both positions successfully 3 decades later when the demands of administration were much greater.

[6] The Holman Committee was appointed by Chancellor Aycock in 1962 as the result of a motion which I made at a Faculty Council meeting. My motion was the substitute for another motion proposed by persons in the Division of Academic Affairs who were attempting to disenfranchise the faculty of Health Affairs, then constituting only about 10% of the faculty but clearly destined to become a near majority eventually. I was influenced into taking this action by Dr. Berryhill, and later served on Dean Holman's committee.

Dr. Berryhill had attended the annual meetings of the Association of American Medical Colleges regularly and had concluded that university administrators were obtaining too much power over faculty members. He felt that faculty members should be shielded as much as possible from arbitrary acts of administrators, and proposed that the faculty develop a constitution and a set of by-laws. The committee he appointed to bring in a proposal was chaired by William Fleming. Walter Hollander was its secretary and Charles Burnett, Nelson Ordway and I, and several others did the donkey work. An instrument was drawn up which, when adopted by the faculty, gave it the right to establish (and dis-establish) departments and to adopt and alter curricula. It also defined the committee of department chairmen as "advisory to the Dean." This instrument has been the faculty's bulwark against arbitrary actions by a Dean or a cabal of department chairmen.

I have often wondered why Dr. Berryhill openly promoted the adoption of this mechanism of governance, one which down-played the importance of the department chairmen he had collected so carefully. Several possibilities suggest themselves. Some of the then current group of chairmen had either opposed him or had remained neutral when the issue was his continuation as Dean. He owed them nothing. Another possibility is that he was expressing his Calvinistic view that power tends to corrupt and must be restrained. The least charitable is that he did not want to be at the mercy of any group with the power to remove him. In any event, he succeeded in establishing a framework of governance for the medical school which leaves pedagogical matters entirely in the hands of the faculty, if they are willing to accept the responsibility.

What might be called Dr. Berryhill's "populist" attitude toward the faculty was shown in other ways. He used regular faculty meetings as a consultative forum and educational mechanism. Agenda were short. Only important issues were discussed. He encouraged free discussion, because he wanted to see how his ideas fitted with those of the faculty. There was always a final agendum, "Remarks by the Dean." Here he expressed his own views and feelings, particularly about political currents in the State and the university. His tone was usually somber, but his analysis often showed that there were potential openings here and there, although perhaps at low probabilities. One left a faculty meeting at 5 o'clock or 5:15 to deal with personal matters feeling that the Dean had his hand on the tiller and would alert us if the need arose.

The rapid growth of NIH occurred during Dr. Berryhill's deanship. The faculty competed well for research funds and our facilities quickly became strained. My memory of the late 1950s and early 1960s is of high scientific productivity under conditions of great crowding.[7]

The only buildings constructed during Dr. Berryhill's deanship after completion of the hospitals[8] were the Research Wing added to MacNider in 1962, and the Biological Sciences Research Center in 1964-65. Temporary relief was obtained during the middle 1960s during Isaac Taylor's deanship when the faculty were authorized to use house trailers for offices and laboratories.[9] The university administration kept a tight lid on additional space for the medical school, and permanent relief was achieved only in the 1970s after the medical student class size had been forced upward by Federal pressure to produce more doctors and local pressure to accommodate the maturing post-war "Baby Boomers."

By 1962, Dr. Berryhill had acquired an Assistant Dean of Students, because he had become too busy to handle student advising alone. When he decided to retire in 1963, statutorily a year early, he asked whether I would be willing to take over the duties of his assistant dean. I looked the situation over and decided that what was needed was a set

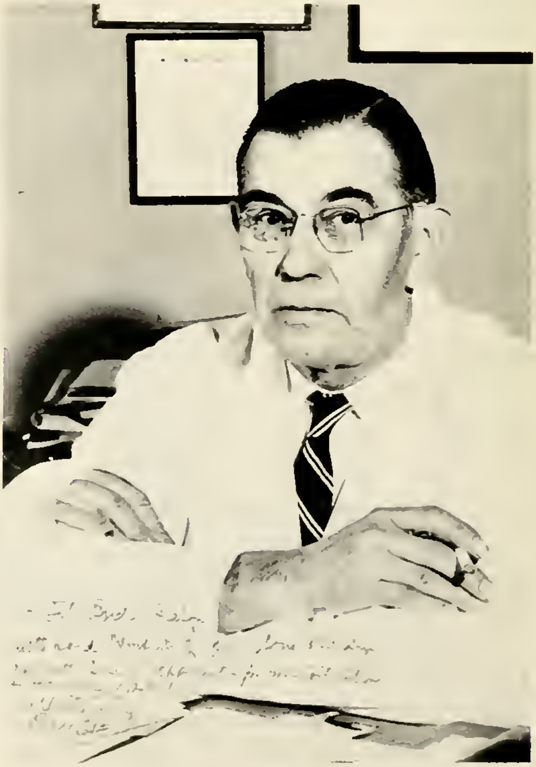

Figure 4. *The retiring Dean, 1964.*

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[7] Professor Parkinson, author of "Parkinson's Law," believes that this is the usual case and that the first sign of decline is the acquisition of "adequate" space.

[8] There were originally three independent hospitals in the hospital complex at Chapel Hill. NCMH was budgeted through the university. Gravely was supported through the Tuberculosis Hospital System, and the South Wing through the Mental Hospital System. Thus, there were three independent budgets and three quite different management styles. These created problems for administrators and opportunities for entrepreneurs.

[9] Dr. Berryhill moved into a trailer after his retirement as Dean, and Dean Taylor's Associate Deans, Chris Fordham and I, also occupied one.

of student advisors, each dealing from admission through graduation with a single student cohort. I agreed to take on the job of supervisor on a part-time basis if he would allow me to organize it the way I wished. He agreed, and this led to a student counseling system which operated effectively until the classes became too large and the student body too heterogeneous.

Final Thoughts about Reece Berryhill

So how shall I conclude my assessment of this remarkable man? Reece Berryhill was highly intelligent, energetic, single-minded and devoted to the University of North Carolina. This devotion provided the focus around which his actions were organized. It also led to clashes with those who were more self-serving. He was an "up-side" person. What I mean is that each of us has either a predominantly "up-side" or a predominantly "down-side" personality, although most of us have a bit of both. The "up-sider" is more concerned about accomplishing his objectives and less concerned about strict observance of rules. The "down-sider" is more concerned about not making administrative errors and less concerned about accomplishing objectives. Business entrepreneurs, artists, and research scientists tend to be "up-siders." Lawyers, accountants, and administrators tend to be "down-siders." My father, who was a businessman, frequently admonished me as a child with this homily: "It's better to be damned for doing something than for doing nothing." Reece Berryhill clearly believed this. Perhaps this was the most basic value which we shared.

SPECIAL ARTICLE

Dr. Berryhill's Third Career, 1964-1978

David S. Citron, M.D.

THESE remarks about Dr. Berryhill are based partly on personal observations and impressions, but mainly on communications from a number of his former students, friends, and associates. Like countless of his other students I considered him a "mentor." In the 1983 Annual Report of the Commonwealth Fund Margaret Mahoney defined a mentor as one who "represents to a young person a commitment to values and modes of behavior that engender a strong sense of personal worth and encourage self-realization." But Dr. Berryhill was a mentor not only for "young persons." His influence on former students prevailed unabated during his entire lifetime. Never having known him intimately, my perspective is limited in comparison with other contributors to this brief history. Nevertheless I hope that I speak for all those whom he influenced far more than he realized.

Dr. Berryhill's plans for a "third career" had begun to germinate long before his resignation from the deanship in 1964. He remembered well that in July 1946 the Committee headed by Dr. William T. Sanger, President of the Medical College of Virginia (already alluded to in Dr. Blythe's biographical sketch) had recommended the establishment of a four-year school of medicine on the Chapel Hill campus, but with a striking proviso, viz:

> "That such a School of Medicine and associated services of the medical school, responsive to the will of the people, be integrated effectively and continuously with a statewide network of hospitals and health centers insofar as these volunteer to cooperate."

Dr. Berryhill had repeatedly expressed the concern that he had not fulfilled that expectation and that this was a debt he owed to the state. His sense of mission to meet the needs of the people of North Carolina for health care became an unflagging drive which was to define the remainder of the trajectory of his life. Now he would express it not as architect and leader of a great medical school but as a missionary with a constituency far beyond the boundaries of Chapel Hill. He would serve the community of North Carolina — a community clamoring for more well trained physicians. To fulfill that need — and his promise — he would extend medical education to the community hospitals of North Carolina, challenging the physicians of those communities and the faculty at Chapel Hill to envision the potential of such an initiative. In the process he would experience disappointments and at times frustration; but these moments would be eclipsed by satisfaction in the knowledge that he had played a predominant role in initiating the state's Area Health Education Centers Program, a national model for the decentralization of health education.

In September of 1964, relieved of the tensions of the deanship, he at last took time for a trip abroad with Norma. It was a working holiday, made possible by a Commonwealth Fund Traveling Fellowship. One of his objectives was to study the British National Health Service in order to determine whether this system was relevant to the then current problems of assuring greater availability and accessibility of health care in the United States — problems which were to be exacerbated two years later with the implementation of the Medicare Program.

During his stay in the United Kingdom he had little patience for sightseeing, preferring to delve deeply into the

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From the Charlotte Memorial Hospital and Medical Center, Charlotte 28232.

intricacies of the N.H.S. through interviews with countless physicians, teachers, and policy makers. Curious about the resurgence of general practice in the U.K., he conferred with Dr. John Hunt (later Lord Hunt), First Secretary of the Royal College of General Practitioners. Earlier, during the visits to the Royal College of Physicians, he had been astounded that some of their most prominent members, conservative in the tradition of British physicians, grudgingly accepted the rationale of the "G.P." as a "respectable" and worthy component of the N.H.S.

The experience abroad provided insights which would later be useful to him as he addressed the problem of attracting more physicians in North Carolina to careers in general practice. While abroad Dr. Berryhill was concerned about the state of affairs at the School of Medicine. A new dean had just been appointed but had not yet "settled in"; and two key departmental chairs were yet unfilled. Following a brief trip to Sandinavia, the Berryhills planned a leisurely return to England via Eurail, with stops at points of interest. But Dr. Berryhill eagerly and often restlessly awaited letters from his secretary, Ms. Dunlap, with news of the Medical School. On one occasion during the trip, impatient to return to Scotland to resume his work, he impulsively decided they should forego a planned stopover in Rome. Later remembering that mail might be awaiting him there, he decided that it would be a mistake to change their itinerary; but the stay in Rome was brief — just long enough to get the mail!

In 1965, following his return to Chapel Hill, Dr. Berryhill became the director of the newly created Division of Education and Research in Community Medical Care. The title, though cumbersome, was accurately descriptive of its function, viz: 1) to develop opportunities for the conduct of research relating to community medical care, and 2) to catalyze the establishment of community-based centers of medical education that could relate to the School of Medicine in ways that would be mutually advantageous. Dr. Berryhill had long been openly critical of the quality of existing graduate medical education activities in the state's community hospitals. I first became aware of this when as a naive fourth year student at the Washington University School of Medicine in 1944 I had decided to apply for an internship at Charlotte Memorial Hospital. It was an imposing, newly built structure which would offer, I thought, a rich exposure to common medical problems and supervision by physicians of local renown.

Dr. Berryhill's response to my request for a letter of recommendation was prompt and laconic: No, he would not write such a letter. The teaching program at Charlotte had not yet proved its worth. I should, instead, remain in St. Lous for graduate training in internal medicine at Barnes Hospital. He would be delighted to write a letter to the departmental chairman. Having never had the temerity to question his judgment on a matter relating to medical education — or almost anything else, for that matter — I accepted his wise counsel.

This was the second unwise career decision from which Dr. Berryhill deterred me. The first related to my application for admission to the School of Medicine at Chapel Hill in 1940. A junior student at that time, I was impatient to get on with medical education and opted for medical school admission without prior completion of requirements for the AB degree. Dr. Berryhill was kind but firm. He found my credentials quite adequate, but he felt it necessary to remind me that being Jewish, I might encounter difficulties in transferring from Chapel Hill to a good four year school for completion of my clinical training two years hence. Completion of a fourth year of college, he believed, would obviate the problem. (In that era racial and religious prejudice, both overt and covert, was known to exist among medical school admissions committees.) He left the decision to me, and I gratefully accepted his advice. This encounter with Dr. Berryhill, painful though it was, first evoked my admiration for him. The willingness to discuss a sensitive issue openly, candidly, and with great kindness was to me an early revelation of his greatness and the beginning of an enduring friendship.

In the late 1950s I called Dr. Berryhill again about Charlotte Memorial Hospital. By then I was practicing in Charlotte and at that particular time was charged with assisting in recruiting of interns. There were now, I told him, a large cadre of young, well-trained physicians in Charlotte — many of them alumni of the University — who were eager to participate in the training of house officers. We would appreciate his assistance in attracting some of "his" graduates for training in Charlotte. Without hesitation and with his customary, unemotional forthrightness he replied "No, David, I can't do that. Charlotte Memorial has a bad reputation to overcome." And he was right. My request was premature if not foolish; and as Glenn Wilson[1] recently reminded me, "Dr. Berryhill suffered fools poorly."

In 1962, Charlotte Memorial Hospital, with the support of the Duke Endowment, appointed a Director of Medical Education, Dr. Bryant Galusha, and with this appointment the character of graduate medical education in Charlotte changed. Formerly unstructured and largely experiential, it began to approach the quality of programs in major university teaching programs. And as Galusha acquired additional full-time faculty, appointments to the house staff became highly competitive. Once high educational standards had been assured, Dr. Berryhill enthusiastically offered his assistance. In May 1963, representatives of the School of Medicine met with leaders of the Charlotte programs to discuss a cooperative relationship. An outcome of this meeting was the agreement of the University's Department of Medicine to assist the Charlotte Internal Medicine Residency by allowing residents from Chapel Hill to spend six to twelve months in Charlotte during the third year of training. With the establishment of the Division of Education and Research in Community Medical Care more extensive affiliations followed, not only with Charlotte Memorial, but also with other community hospitals throughout the state.

The evolving orientation of the Division to the North Carolina Area Health Education Centers Program, from 1965 to 1972, was one of uncertainty, experimentation, and struggle. It was perhaps more complex than establishing a new medical school, for no template existed for such an organization except in Dr. Berryhill's mind. As early as 1950, referring to North Carolina's "Good Health Program," initiated by the legislature several years earlier, he said" . . . with the active cooperation and participation by the three medical schools in the State, many educational and service opportunities will be available to the medically isolated communities in the State. If adequate funds continue to be supplied our medical personnel, medical service, and hospital shortages should in a relatively short while be alleviated."[2]

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[1] Associate Dean for Community Health Sciences, The School of Medicine.

Recognizing the educational validity of providing clinical experiences to students and residents which would be highly relevant to and consonant with their eventual practices, and realizing that the resources for clinical teaching in Chapel Hill would be taxed as classes in the medical school were enlarged, he sought to extend education in the health professions to communities throughout the state.

In retrospect I marvel at the abilities of Dr. Berryhill and those who preceded him as deans of the "two year school" to provide effective teaching with faculties which by today's standards would be ludicrously small. But resources at his disposal for conducting the program of the new Division were equally thin.

Dean Isaac Taylor's letter of appointment assured Dr. Berryhill that he would have ". . . a staff consisting of one or more professional assistants and appropriate nonprofessional personnel" and that "the important work of the section (would) eventually require an annual budget in the range of hundreds of thousands of dollars."[3] But the initial budget was meager and the entire professional staff, in addition to Dr. Berryhill, consisted of Dr. Carl Lyle of the Department of Medicine and Dr. Robert Huntley of Preventive Medicine. In retrospect their accomplishments in the early days of the Division were crucial to its survival. Lofty though the concept may have sounded, reaching out to communities to help them improve health care was fraught with difficulties, viz. the sheer size of the state in relation to the modest resources of the Division; the inertia of key faculty members in the School of Medicine, who were occupied with agendas given higher priorities; the uncertainty of future funding of the Division; the ambivalence of community-based physicians toward perceived incursions of their domains by the University; and unrealistic expectations of many communities in relation to their ability to recruit and retain physicians. (The latter problem was succinctly summarized by one of my colleagues, viz. "If a town can't support a first class barber shop it surely won't support a doctor!")

Dr. Berryhill understood fully what opportunities lay ahead, but also what pitfalls. He realized that progress would be made only if leadership could be developed from within the medical community of the state. His genius for sowing the seed of an idea in the minds of others — and deluding them into believing that it was theirs — was of inestimable value. As Bryant Galusha recently reminded me, most people don't care for the "company car" as well as their own. What he meant was that whether it is an idea or an object, pride of "ownership" affects behavior. And Dr. Berryhill was quite willing to forego personal recognition for whatever accomplishments might be achieved in order that community leaders might receive the plaudits — and thereby be more highly motivated. The typical Berryhill approach was "I'm not telling you what do do, but you might want to consider. . . ." As he traveled throughout the state with Lyle, John Payne,[4] Robert Smith,[5] and other close associates in the Division his objective was to identify and reinforce local leadership and delicately channel it, the ultimate goal being the development of local educational programs of high quality. The history of the Division, its relation to the Regional Medical Program, its growth, and its subsequent relationships to the AHEC Program has been written elsewhere.[6] Flourishing under the leadership of its present director, Eugene Mayer, M.D., its presence is felt in each of the 100 counties of North Carolina. Its objectives are articulated with the state's current needs for health professionals. Operating contracts with the four schools of medicine in North Carolina have enabled the establishment of 300 new residency positions in the "primary care" specialties of family practice, internal medicine, pediatrics, and obstetrics/gynecology — many of them in community hospitals geographically remote from the medical school with which they are associated. And programs are conducted in dentistry, pharmacy, public health, nursing, and allied health, providing community-based educational opportunities in these disciplines. A statewide network of library/learning resource centers facilitates access to current information by all health professionals. And a fleet of airplanes facilitates transport of students and instructors to and from the UNC-CH campus and educational sites within the nine regional AHECs.

Although Dr. Berryhill resigned in 1969 from the directorship of the Division and in 1971 from active participation in its activities, his influence remained. Both Robert Smith and Glenn Wilson, who succeeded him, acknowledge that influence. Says Wilson, "When I arrived in Chapel Hill in 1970, knowing very little about the State and its health care problems, he travelled with me, introduced me and said that what I was doing was a good idea. Without his great credibility and his saying 'I'm involved' it might have taken years for AHEC to evolve; in fact without his reputation and good will among physicians in the State it might have failed. His Presbyterian sense of integrity and his commitment to the people of North Carolina made it work. He took an extraordinary chance with a 'kid' from Ohio and gave me his endorsement. I respected him totally; and although we were close friends I could never address him by his first name."

Smith, who also valued Dr. Berryhill's friendship and sponsorship, recalls vividly their many long drives to small communities on behalf of the Division. The hours passed quickly as Dr. Berryhill told endless stories about his ancestral family, his ties with Scotland, the politics of North Carolina, and the early years of the School of Medicine. Dr. Berryhill was at his best as a historian, relating his prodigious memories of the experiences of a lifetime to whatever problems were at hand.

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[2] *The News and Observer*, Raleigh, 2/26/50.

[3] I. M. Taylor to Berryhill, December 26, 1967.

[4] Payne is now Deputy Director of the N.C. AHEC.

[5] Smith later became Chairman of the newly-created Department of Family Medicine and is now Chairman of the Department of Family Medicine, University of Cincinnati.

[6] Schnorenberg B.: "The Division of Education and Research in Community Medical Care — 1966-71," (Unpublished papers in archives of the North Carolina AHEC Programs).

Many honors were bestowed on him during his "second career." Beginning with the O. Max Gardner Award in 1964 (as the member of the consolidated University of North Carolina faculty who had made "the greatest contribution to the welfare of the human race" during that academic year) there followed his appointment as Sarah Graham Kenan Professor in 1968,[7] an honorary doctorate from the University of North Carolina in 1976, the dedication of Berryhill Hall in 1973, and his induction as a Master of the American College of Physicians, the most coveted membership status of that organization.

In 1971 friends and former students in his native Mecklenburg County honored him at a banquet on the occasion of his retirement with announcement by his close friend, Dr. James M. Alexander, of the establishment of the Berryhill-Mecklenburg Medical Student Scholarship. In accordance with Dr. Berryhill's wishes, the scholarships were to be granted on the basis of need, priority being given to residents of the Mecklenburg County area and to American Indians, whom he wished to encourage to study medicine.

When he died, on New Year's Day in 1979, William Friday, President of the University of North Carolina, calling him "one of the University's noble sons," said "His concern was the good health of all citizens, and his dedication was total."

As his friend Cheree Briggs Cleghorn wrote of him in 1973, "Dr. Reece Berryhill is an eloquent testimony to the best we can be."

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[7] He was the first faculty member of the School of Medicine to be so honored.

SPECIAL ARTICLE

Dr. Berryhill, My Boss: 1942-1964

Sarah Virginia Dunlap

I first met Dr. Berryhill on the front steps of South Building (the administration building for the University) at seven o'clock in the evening for an interview for the position of secretary in his office. We talked for about forty-five minutes sitting on the steps. He had come back to the campus for this purpose from working in his garden. I was to learn later the importance of gardening in his daily life — flowers, vegetables, shrubs, and trees, and, as he said once, "the opportunity to bury deep in the earth frustrations and even, at times, enemies." Up to his final illness, his garden and plant room were prodigious.

Dr. Berryhill loved the University — more than anyone else I have known — and expressed it by word and deed, through difficult as well as good times. To put it quite simply, Dr. Berryhill *worked* for The University of North Carolina. His vision for the University was high. He understood what should be its goals and ideals and what were its problems.

He had a sense of responsible commitment. Almost from my first week in his office in 1942 I was aware that he was working toward expanding the two-year school into a four-year medical school. He was a consistently busy man who used his time (when he wasn't teaching and administering) to think, write, and contact alumni and friends of the University about his goals for the School of Medicine. Many of the members of the General Assembly and people occupying high positions in state government at that time were former classmates or friends he had known in the University. They were people who loved the University, too, and who were interested in helping it fulfill its obligations to the people of the State.

It would be hard to enumerate the many ways in which Dr. Berryhill served his science, his University, his colleagues, his students, and his friends. Two dominating facets of his personality, to me, were his integrity and his lack of ostentation.

One afternoon while seeing patients at the University Infirmary (an appointment he continued to hold for several years after he became Dean of the School of Medicine), he received a telephone call that his barn was on fire. He did not have his personal automobile at the Infirmary on that day; he had picked up a state car to drive to a nearby town so that he could give a speech for the University early that evening. He would not use the state car to drive the several miles to check on his burning barn. Rather he ran from door to door until he found a doctor who would lend him a car.

When I remember Dr. Berryhill, I remember images:

> standing in the hall smoking a cigarette and wearing a white coat that was a little short for him, talking to students or faculty;
>
> sitting at his desk, cigarette in hand, writing a quick, brief note to a student, a faculty member, a friend, an

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From the Secretary of the University of North Carolina at Chapel Hill 27514

acquaintance who needed a word of encouragement or a word of praise or congratulations;

bringing to the girls in the office the first old-fashioned blue hyacinth of the spring from his garden;

returning to the office a day early from vacation with two or three or four legal-size yellow pads completely filled, back and front, with his handwriting;

making daily visits to friends and acquaintances who were patients in the Hospital, whether the janitor or a figure of state or of national importance, usually with a rose or small bouquet of flowers in hand;

delivering remembrances on Christmas Eve to the homes of his office staff;

pacing the floor on a snowy and icy afternoon watching and waiting for the bus (called Black Maria by the students) to return from Durham or McCain where the second-year students had gone for introductory clinical training (before the expansion of the School).

Dr. Berryhill's handwriting, as is true with many physicians, was difficult to read. On one occasion a student in his Physical Diagnosis class brought an examination paper to the office and said he could not read the note Dr. Berryhill had written on it. I read it for him: "Mr. Lewis, I will not waste my time trying to decipher such terrible handwriting. Please see me. W.R.B."

There was no small talk in Dr. Berryhill's conversation; all that he said had a point and it was not an isolated point. Matter-of-factness and evenness was in his voice and written style. He did not pause when he spoke. There were no hems and haws. He spoke as he wrote, always grammatically correct and coherent.

He was a tall man with great dignity — a dignity which characterized everything he did and which, possibly, was why students and young faculty and staff stood in real awe of him — that is until they got to know him. He had a genuine talent to reach out and establish a relationship of appreciation and trust.

Even though his feelings toward individuals were warm, he was a gentleman of the old school in the matter of dignity in his office procedures. One member of his staff, Miss Helen Jane Wettach, was the daughter of two of his closest friends and he, of course, saw her often socially in the Wettach home. In the years she was in his office, however, he never failed once to address her as "Miss Wettach."

The medical students came first with Dr. Berryhill. He knew each student by name wherever and whenever he saw him after his initial meeting. He was not sentimental with students. He never flattered them; he never compromised his standards or his convictions to gain their approbation. He was to the students, as he was to his colleagues, the embodiment of the ideals of learning and civility.

His caring began as they progressed through medical school. If a student wasn't performing well, he was invited to see the Dean in his office. Dr. Berryhill was concerned to find out the reason. A visit with the Dean was a greatly dreaded event by the students; they often left visibly shaken. I learned to know that this, most likely, was due to their great respect for him and their own feeling of having let him down.

In his counseling with students about their postgraduate training and professional life, he was greatly influential in shaping their careers. They never stopped seeking his careful, prudent, and sound advice. One of his real pleasures was keeping in touch with their accomplishments and with their families.

The outstanding faculty assembled at the time of the opening of the four-year school was really Dr. Berryhill's creation. There was a real sense, although he would not wish me to say it, in which that medical school was his, not just its building, but its spirit and quality.

In all that he undertook he was sustained and supported by his wife Norma. As Dr. Berryhill remarked on one occasion, "She did more than anybody." That included entertaining faculty and their families and medical students and their families. During the period of expansion from a two-year to a four-year school, she assisted new faculty in finding housing, welcomed them on the first night in town with flowers and casseroles of hot nourishing food, organized support groups for wives, and on and on.

Dr. Berryhill was a loyal and loving member of his family and a staunch friend. He was devoted to his University, to Chapel Hill, to the State of North Carolina, his country, and his profession. He was, above all, unswervingly loyal to the truth and he was a man of deep religious convictions.

I shall be forever grateful for the privilege of working with him. He greatly influenced any life he touched.

Dean Stuart Bondurant has announced the formation of a committee to plan for a distinguished lecture to be given annually at a convocation of the medical faculty of the University of North Carolina. It will be called the Norma Berryhill Distinguished Lectureship. Contributions to support the lectureship are now being sought. Anyone wishing to may send a contribution to the Norma Berryhill Distinguished Lectureship, Medical Foundation of North Carolina, Inc., MacNider Building, UNC School of Medicine, Chapel Hill 27514.

EDITORIAL

The Development, Justification and Future of a Community Hospital Internal Medicine Training Program

Emile E. Werk, Jr., M.D.

THE development of a successful training program in Internal Medicine in a community hospital is a challenging undertaking. The Area Health Education Center (AHEC) Program of the University of North Carolina and New Hanover Memorial Hospital initiated this effort in Wilmington, North Carolina in 1972. The primary motivating factors were the basic goals of the AHEC program: development of regional educational centers and recruitment of physicians to underserved areas. Several groups participating in this venture had other aspirations. These included hopes for financial support, prestige, enhanced care of indigent patients and improved university-community relations. Formidable opposition existed, fed by the fear of a "university takeover," and worry about a shortage of hospital beds, interference with patient care, and overextension of hospital service facilities. The day-to-day requirements of a training program that include staff and administrative commitment, time, and acceptance of trainees and their needs were not generally appreciated. In the center of this foray was the earnest desire by those immediately responsible to develop the best training program possible. It was clear that working toward this goal was not like a crash program to send an astronaut to the moon with a collection of groups all totally committed to a single, unswerving effort.

Being a part of this challenge from the beginning to the present has provided me with a unique experience lasting over 12 years. Indeed, recent statistics gathered by the Association of Program Directors in Internal Medicine[1] indicate that the average length of service of existing Program Directors was 5 years and the average age was 49 years; the incumbent is near 2 standard deviations on both counts.

Progress has been made. As the report of Ungaro and Gonzalez in this issue of the *Journal* documents, 23 trainees have completed 3 years of internal medicine training at New Hanover Memorial Hospital. Fifteen of these physicians are practicing in North Carolina, almost half in small towns. These physicians are highly regarded in their respective communities. Thus, it appears that a degree of success has been achieved. What has this depended upon? A circuitous course of compromise, coupled with a strong sense of determination and a spirit of mutual respect have all been involved. Strong support from the University of North Carolina, the AHEC administration, the hospital administration and the talented local full-time faculty have all been vital. But the most central factor of all has been the unrelenting support of our community's internal medicine practitioners. A small number of actively teaching clinical faculty has steadily increased to form an enthusiastic and sizable group of subspecialists and generalists. Many are younger physicians who have been attracted to the area by the desire to participate in teaching as well as to enjoy a sophisticated medical environment in a coastal location.

What about the quality of trainees in such a young program? Certainly this is an important question. Competition among training programs for top notch medical school graduates is keen. It might be said that given the requirements and inspection process of the Residency Review Committee in Internal Medicine and the clinical skills demands set forth by the American Board of Internal Medicine, most programs today are of high quality. Recruitment has been and undoubtedly will continue to be one of the major challenges in community hospital programs.

Is the community hospital truly justified in training physicians in internal medicine in comparison with the highly sophisticated university medical center? Having closely observed both sides, my biased response is an emphatic "yes." Community program trainees acquire superior clinical skills that enable them to deal with common disorders, decision making, and cost benefit analysis. They have a unique opportunity to develop strong humanistic traits. It is my impression that the cost of medical care provided to our housestaff patients is not greatly different from that of private patients in this hospital. This is in contrast to the considerable difference found in a recently published Stanford study.[2] Moreover it must be emphasized that many clinical practitioners in community hospitals have the ability and capacity to be exceptional teachers and role models. Our residents have initiated the E. Thomas Marshburn award which will be given yearly to the third year resident who best exhibits the "outstanding qualities of an internist as exemplified by Dr. E. Thomas Marshburn." A practicing internist, Dr. Marshburn has been an active, popular teacher since the program was

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started. He is a prime example of a community teaching resource that could not be utilized if there was no teaching program.

The biggest challenge of all probably lies ahead. Can community hospital training programs survive in the face of physician surplus, the increased cost of health care, federal regulations and the financial drain on community hospitals? Those of us who have seen the advantages of a community hospital program become more and more apparent would hope so. The collapse of such programs would be most unfortunate. The money and effort already expended to develop them to their current level would be lost. In addition a valuable resource for training highly skilled clinicians for North Carolina would be missing.

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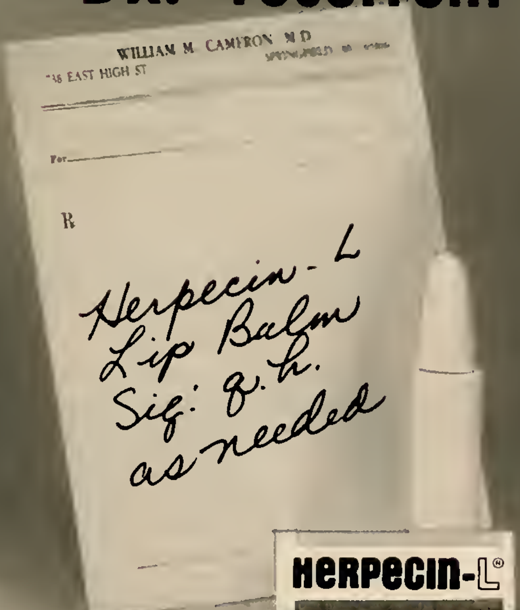

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SCIENTIFIC ARTICLE

Isolated ACTH Deficiency; a Not-so-Rare Syndrome, with Variable Manifestations

Jorge J. Gonzalez, M.D. and Emile E. Werk, Jr., M.D.

• *Four patients are presented with isolated adrenocorticotrophin deficiency and a variety of symptoms.*

SINCE the description of the first case of isolated adrenocorticotrophin (ACTH) deficiency by Steinberg et al in 1954,[1] another fifty or so cases have been added to the world's literature. As its name implies, this syndrome is characterized by deficient ACTH secretion in the presence of an otherwise normal hypothalamus pituitary unit.

Clinically isolated ACTH deficiency appears more often between the fourth and sixth decade. The symptoms are nonspecific, and the clinical presentation may be quite variable. In sharp contrast with classical Addison's disease, these patients are rarely pigmented and lack the "telltale" hyperkalemia so chacteristic of the mineralocorticoid deficiency of Addison's disease. In addition, patients with this syndrome appear to be more resistant to stress than patients with Addison's disease. The higher resistance to stress could be related to the preservation of the mineralocorticoid function and/or the higher residual glucocorticoid secreting capacity present in these patients.

These characteristics of this syndrome make it difficult to recognize and it is not rare for these patients to have several previous hospitalizations before the definite diagnosis is made. We observed four cases of isolated ACTH deficiency over the last few years. We believe that they demonstrate the heterogeneity of symptoms and the different kinds of presentation of this syndrome.

Case 1

D.M., a 74-year-old black man, was admitted to the hospital for seizures which had started several months previously and increased in frequency. There was no history of trauma. He had been followed in the medical outpatient department for an "aplastic anemia" thought to be related to insecticide exposure. On physical exam his blood pressure was 70/40 and he had a normal pulse and temperature. He appeared thin, wasted, and apathetic. There was no increased pigmentation. Genitalia and sexual hair were normal and the prostate gland was slightly enlarged. Pertinent laboratory findings included a hemoglobin of 11.2 with 2800 white cells and normal differential. Blood glucose was 57 mg/dl, urea nitrogen 6 mg/dl, serum sodium 118 mEq/L, potassium 4.4 mEq/L, chloride 81 mEq/L, CO_2 25 mEq/L, creatinine 1.1 mg/dl, and cholesterol 155 mg/dl.

The patient was given intravenous fluids and diphenylhydantoin and an endocrine evaluation was instituted. He remained weak and drowsy. Eight days later he became stuporous and his blood sugar was 15 mg/dl. Intravenous hydrocortisone was started, followed by maintenance oral hydrocortisone. Marked improvement occurred. Levels of serum electrolytes and blood sugar became normal. The endocrine tests prior to steroid treatment showed zero cortisol levels with one ACTH level of 56 pg/ml (normal <100). After intramuscular Cortrosyn, plasma cortisol remained zero and aldosterone increased slightly from 2 to 3 ng/dl. An upright plasma renin activity level was 0.3 ng/ml/hr. Levels of thyroxine, sleep stimulated growth hormone, LH and testosterone were normal. Subsequently he was followed in the outpatient department with continued gain in strength and weight. Blood pressure increased to hypertensive levels requiring mild diuretic therapy despite low maintenance dose of prednisone. Six months later he was admitted for a three day ACTH stimulation test. During the readmission evaluation he was given aqueous ACTH 40 U intravenously over 8 hours for 3 days. Plasma cortisol concentration increased stepwise to 12 μg/dl, urinary 17-hydroxycorticosteroids to 3.7 mg/24 hr, and free urinary cortisol to 34 μg/24 hr. Plasma aldosterone was 11 ng/dl and PRA was 13 ng/ml/hr after furosemide administration. Radiological studies of the pituitary were normal. He has continued to do well on prednisone replacement. His hematological indexes normalized after replacement therapy.

Case 2

W.W., a 48-year-old white man, was admitted to the hospital in October 1972 because of progressive weakness and dizziness. He stated that he had been sick on and off for three years. In 1969 he had a subtotal gastrectomy at another hospital presumably for peptic ulcer disease. Since then he had repeated episodes of nausea, vomiting, and diarrhea, requiring several hospital admissions. In 1970 at another hospital he was said to have unexplained "hyponatremia" and weight loss. In 1971 and early 1972 he was admitted to this hospital with the diagnoses of 1) dumping syndrome, 2) psychogenic food intolerance, 3) broncho-

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pneumonia, and 4) positive serology for syphilis, treated. During the 1972 hospital admission, a serum sodium of 105 and potassium of 5.1 mEq/L were noted and treated with intravenous saline.

Physical exam revealed a poorly nourished white man appearing very weak and older than his stated age. Blood pressure was 110/60 supine and the systolic pressure with a pulse pressure of 0 on standing decreased to 90. Pulse was 100. There was no increased pigmentation. Genitalia and sexual hair were normal.

Laboratory tests showed a hemoglobin of 10.1 and 5300 white blood cells. Serum sodium was 116 and potassium 5.3 mEq/L. Chest x-ray showed pleural thickening and emphysematous bleb formation.

Hypopituitarism was suspected and the following endocrine tests were performed: Serum thyroxine 7.3 μg/dl (normal: 3.3-8.9), plasma renin activity upright 1.18 ng/ml/hr (normal: 1.0-5.0), plasma cortisol at 8 a.m. 12 μg/dl (normal: 7.0-23.0), and at 8 p.m. 10 μg/dl (normal: 5.0-15.0). The serum cortisol increased from 9 μg/dl to 42 mg/dl after 8 hours of ACTH infusion. An insulin tolerance test (0.1 μ/kg) (table 1) showed sustained hypoglycemia with poor responsiveness in cortisol but a rise in the level of growth hormone. Skull x-ray was normal.

The patient was treated with 12.5 mg cortisone acetate twice daily and followed in the outpatient clinic. There was a dramatic improvement in strength and appetite. Weight increased from 93 to 105 lb over the next several weeks. The serum sodium concentration was 141 and potassium 4.5 mEq/L. Additional laboratory evaluation during his follow-up revealed a testosterone level of 1000 ng/dl and a normal prolactin level.

Approximately 6 years after the diagnosis, the patient developed a macrocytic anemia, with a low vitamin B_{12} level, a positive Schillings test, positive anti-parietal cell antibodies and negative anti-intrinsic factor antibodies. An upper GI series revealed a 60% gastric resection with a Billroth II procedure. Gastric biopsy showed atrophic gastritis with absent parietal and chief cells. It was not possible to differentiate between B_{12} deficiency secondary to gastrectomy or true pernicious anemia. The patient was treated with monthly shots of vitamin B_{12} and his blood counts became normal.

Case 3

M.A., a 49-year-old white woman, was referred January 1982 to the endocrine clinic by her local practitioner because of hypothyroidism. She felt that she had gradual weakness for as long as 15 years which became much worse during the previous year and was accompanied by fatigue, cold intolerance, deepening voice, axillary hair loss and menstrual irregularity. She had had five uneventful pregnancies, the last 15 years previously. All five children were living and well. A unilateral ovary and tube had been removed in 1968 and appendectomy performed in 1959. There was no family history of autoimmune disease. Her mother had breast cancer.

Table 1
Insulin Tolerance Test (0.1μ/kg IV) in Patient 2

	Glucose (mg/dl)	Cortisol (μg/dl)	Growth Hormone (ng/dl)
Fasting	75	6	2
30′	30	8	2
60′	26	8	3.4
90′	27	7	3.7
120′	31	7	4.6

The physical examination revealed a weight of 162 lb, a height of 63″, and a normal pulse and blood pressure. The patient appeared pale, puffy and sluggish. The skin was dry and thickened without pigmentation. Axillary hair was sparse. The thyroid was not felt. Deep reflexes showed delayed relaxation.

Thyroid function tests revealed a T_3 resin uptake of 0.68 (normal: 0.80-1.20), a T_4 of 4.7 μg/dl (normal: 4-12), a free thyroxine index (FTI) of 3.7 (normal: 5-12) and TSH level of 16 μU/ml (normal: <5). Antithyroglobulin antibodies were positive with a titre of 1600 and microsomal antibodies were negative.

The patient was placed on increasing dosage of 1-thyroxine. Over the next several weeks she noted minimal improvement in energy and decreased constipation but as the dosage of 1-thyroxine was increased above 0.075 mg/day she felt even weaker. Normal levels of thyroxine, 8.4 μg/dl, TSH 4.5 μU/ml, sodium 143 mEq/L, and potassium 4.2 mEq/L were noted. A morning level of cortisol was low, 5.3 μg/dl (normal: 6-20). We planned to evaluate the patient further for adrenal insufficiency but she did not return for 6 months.

At that time she stated she had discontinued the 1-thyroxine and felt persistently weak. Excessive menstrual bleeding had occurred. She appeared again pale, puffy and weak. She was admitted to the hospital for further endocrine evaluation. Routine laboratory tests and serum electrolytes were normal. The patient was taking 1-thyroxine 0.05 mg daily when these tests were done. A short ACTH stimulation test showed the following values.

	Basal	30 Minutes after Cortrosyn
ACTH (pg/ml-	<20	
Cortisol (μg/dl)	0.5	4.7
Aldosterone (ng/dl)	6	24

An insulin stimulation test and a metyrapone test were then performed (see table 2). The ACTH, cortisol and deoxycortisol responses confirmed a deficiency of ACTH. The growth hormone response to insulin hypoglycemia was flat. Retesting of the growth hormone axis with other stimulatory agents is pending. Estradiol, FSH, LH levels showed normal premenopausal concentrations. A CT scan of the head and polytomograms of the pituitary fossa were normal.

The patient was discharged from the hospital to take prednisone 5 mg in the morning and 2.5 mg in the evening, and 1-thyroxine 0.05 mg each morning. Follow-up in the outpatient department revealed that the patient felt much

Table 2
Insulin Tolerance, TRH Stimulation and Metyrapone Test Results in Patient 3

Insulin Tolerance (0.1 μ/kg IV) and TRH Stimulation Test (200 μg IV)

Time	Glucose (mg/dl)	Cortisol (μg/dl)	Prolactin (ng/ml)	ACTH (pg/ml)	TSH (μU/ml)	GH (ng/dl)
0	76	0.9	14	< 20	7.7	1
30	154*	1.2	61	< 20	27.3	1
60	111	1.1	44		18.6	1
90	73	1.0	29	< 20	16.0	1

Metyrapone Test

Metyrapone, 2 gr PO at midnight
8 a.m. ACTH < 20 (normal: 180-900 pg/ml)
8 a.m. ACTH deoxycortisol 0.4 μg/dl (normal: 7-22 μg/dl)

* 25 ml of D50/W given intravenously due to severe hypoglycemic symptoms

improved. Her weakness was ameliorated. Over several weeks the prednisone dosage was decreased to 4 mg in the morning and 1 mg in the evening, and she was able to tolerate 0.1 mg l-thyroxine daily. Menses became regular at 4 week intervals.

Case 4

This 25-year-old black woman was admitted to the hospital with hypotension, fever, and lethargy. She had taken oral penicillin during the previous 48 hours. She had complained of sore throat, fever, and headache. She had been taking INH for 6 months for a recent PPD conversion. Her menstrual periods had been normal. Her temperature was 102.5°F. Stiffness of the neck and a positive Brudzinski's sign were noted. No other abnormalities were found.

CT scan of the head was normal. A lumbar puncture showed a protein of 56 mg/dl with 3 white cells and a glucose of 26 mg/dl. Smear and cultures of the CSF were negative. Admission laboratory tests showed a blood sugar of 60 mg/dl. Serum electrolyte levels were normal, with the exception of a bicarbonate of 17 mEq/L. Her serum creatinine was 1.6 mg/dl. A cortisol level was 1.7 μg/dl with a simultaneous ACTH level of less than 20 pg/ml. The patient was treated with a broad spectrum antibiotic and given methyl prednisolone.

She responded well to therapy. Glucocorticoids were discontinued after 24 hours, and 6 days later she continued to have a low serum cortisol with undetectable ACTH level. Urinary free cortisol was less than 2 μg/24 hr. Thyroid antimicrosomal and antithyroglobulin antibodies were negative.

Detailed endocrinological evaluation of this patient is being published in detail elsewhere.[2]

This evaluation confirmed the diagnosis of isolated ACTH deficiency. The patient was started on glucocorticoid replacement and has done very well since then.

Discussion

In their extensive review, Stacpoole et al[3] found that hypoglycemia was the most common clinical finding reported in these patients (56% of cases). Hyponatremia on the other hand was the least frequent clinical manifestation encountered. The frequency of weight loss, hypotension, anemia, weakness, nausea and vomiting, and inability to excrete a water load was found to be between the above mentioned extremes. In contrast to this distribution, two of the four patients presented here had hyponatremia and there was only one episode of spontaneous hypoglycemia. One patient had mild hyperkalemia. Hypotension was seen in three of the four patients.

Patient 3 had a flat response of growth hormone to hypoglycemia. This suggests a "combined deficiency" rather than isolated ACTH deficiency. However, it is well known that a small fraction of normal people fail to demonstrate stimulation of growth hormone with hypoglycemia.[4] The definitive diagnosis of growth hormone deficiency requires at least two provocative tests to evaluate growth hormone secretion.

The clinical heterogeneity of the isolated ACTH syndrome might be accounted for by differences in underlying cause. ACTH deficiency can originate within the pituitary or in the hypothalamus or, at least in theory, in higher encephalic centers. The fact that some patients with isolated ACTH deficiency respond to vasopressin with an increase in ACTH[3] suggests that a fraction of these patients have an intact pituitary. It is likely that with the use of the newly isolated corticotropin releasing factor (CRF) a better delineation of the origin of the syndrome will be possible. It has been reported recently that the CRF stimulation test holds promise in distinguishing a failure at the level of the pituitary from one that originates in the hypothalamus.[5] Unfortunately, pathological studies in this entity are practically nonexistent.

The coexistence of primary autoimmune hypothyroidism with isolated ACTH deficiency has been reported previously.[6] One of the patients in this series presented with the classical clinical situation of hypothyroidism which gets worse after thyroid replacement, and ACTH deficiency was ultimately diagnosed. Conventional endocrine wisdom has taught us to suspect coexisting Addison's disease in these patients (Schmidt's syndrome). The patient presented here and the similar patients reported in the past demonstrate that in clinical medicine exceptions to the rule are common.

The coexistence of Hashimoto's thyroiditis with isolated ACTH deficiency, and the pathologic findings of both lymphoid hypophysitis and lymphoid thyroiditis in one previously reported patient[7] suggest an autoimmune mechanism for some of the cases of ACTH deficiency. In patient 2 it was impossible to differentiate between true pernicious anemia and anemia secondary to gastrectomy. In any case, it appears possible that isolated ACTH deficiency due to lymphoid hypophysitis will add in the future to the evergrowing list of autoimmune polyglandular failure syndromes.

We think that isolated ACTH deficiency may be more common than reported up to now, and we hope that this report will stimulate the detection of new cases in our state.

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SCIENTIFIC ARTICLE

Hereditary Angioedema as a Cause for the Non-Surgical Acute Abdomen

John D. Hunter, M.D.

- *Severe abdominal pain can be the only presenting feature of hereditary angioedema.*

ACUTE severe abdominal pain is a major challenge in any medical practice. This is particularly true when a previously healthy young person is in considerable distress without a history, physical sign, or laboratory abnormality that points to a surgical problem.[1] What should be included in the non-surgical evaluation? When are laboratory tests cost-effective to diagnose the rarer medical causes of abdominal pain? When is the "organic" workup complete and when should psychiatric evaluation begin?

Hereditary angioedema is a medical cause, albeit uncommon, of acute, severe abdominal pain.[2, 3] This autosomal dominant deficiency of C_1 esterase inhibitor ($\overline{C}_1$INH) in the complement cascade usually presents with painless nonurticarial swelling, sometimes causing fatal laryngeal edema. However, striking abdominal discomfort can be the sole initial feature.[4]

A patient with hereditary angioedema, therefore, serves as an excellent example of a rare medical cause of the non-surgical acute abdomen. With a reasonable index of suspicion and careful clinical analysis, extensive diagnostic radiologic and invasive procedures, including laparotomy, can be avoided.

Case Report

A 20-year-old white married woman was admitted for the second time in a month for acute severe abdominal pain. Four weeks previously she had developed mid-abdominal sharp grabbing pains and had been treated for presumed pelvic inflammatory disease. However, within 48 hours she was hospitalized by her gynecologist with persistent pain. She had no fever and a relatively normal abdominal exam, but there was a suggestion of right-sided tenderness with fullness in that area on pelvic exam. X-ray of chest and abdomen and blood studies were all normal, with the exception of a very minimally elevated SGOT. She underwent diagnostic laparoscopy which suggested a ruptured corpus luteum cyst. Her pain subsided after about 96 hours.

She remained pain-free for three weeks but was hospitalized again with the same mid-abdominal sharp grabbing pain, occurring suddenly, unassociated with bowel or bladder symptoms, nausea, vomiting, fever, chills or bleeding. She was quite uncomfortable, but had minimal non-focal guarding. The pain subsided again in four days.

On this occasion, however, she had puffiness about the cheeks and forearms. Though the patient had no prior history of abdominal pains, she did relate intermittent nonspecific puffiness of the face and extremities. She denied previous cardiac, renal or liver problems, or illicit drug use. She was taking no medications other than Tylenol, and no contraceptive pills. She drank no alcohol. There was no allergic history and she denied emotional stress.

More careful history revealed that several family members had multiple abdominal surgical procedures, especially cholecystectomy, but often with apparently minimal pathological findings, and with persistent pain after surgery.

From the Department of Medicine, New Hanover Memorial Hospital, Wilmington 28401.

Table 1

Clinical Characteristics of Hereditary Angioedema Attacks in 28 Patients

	Patients %
Precipitating factors	
Trauma	54
Anxiety or stress	43
Signs and symptoms	
Peripheral angioedema	96
Facial angioedema	85
Pharyngeal angioedema	64
Recurrent abdominal	
Pain	93
Nausea or vomiting, or both	88
Diarrhea	22
Rash	26
Most common disease manifestation	
Peripheral angioedema	79
Abdominal pain	21

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Subsequent evaluation revealed normal blood counts, urinalysis, serum amylase, and chemical screen. An upper GI series, small bowel x-ray, oral cholecystogram, barium enema, gall bladder and pancreatic ultrasonography and intravenous pyelogram were normal. Urinary drug screen and Watson-Schwartz urinary tests were negative. However a low C4 level, elevated complement decay rate of 85% (CH_{50} titer after incubation in a low ionic strength buffer), and $\overline{C}_1$INH level of 5 mg% (20% of normal, by anti-serum method) were discovered.

The patient has now been pain-free for over a year on no specific therapy. Family screening subsequently revealed her mother to have a similar history of abdominal pains and swelling and to have $\overline{C}_1$INH deficiency. Further family screening is pending.

Discussion

Hereditary angioedema is a rare but important clinical entity. Death occurs in 14-30% of patients, who are often young, usually from acute laryngeal edema and obstruction.[2, 3, 5] Attacks are largely preventable once the diagnosis is made. But in a study of 30 patients from the National Institute of Health it was found that the median duration of symptoms before the diagnosis was established was 21 years.[2]

Certain clinical clues should raise the physician's index of suspicion (table 1).[2] Over 85% of patients relate a history of recurrent unexplained bouts of painless, nonpitting, nonurticarial, nonpruritic edema of the face or extremities. Since inheritance is autosomal dominant with variable penetrance, a family history of compatible symptoms is found in 75% of patients. Frequently this includes repeated surgical operations such as cholecystectomy, appendectomy and hysterectomy, followed by recurrent abdominal pain. Many patients are labeled with functional bowel symptoms or neurosis.

The typical patient is a white young person (90%) of either sex (two-thirds are symptomatic before age 13 with

Table 2

Medical Conditions Causing the Acute Abdomen

Familial Metabolic

- Acute intermittent porphyria
- Familial hyperlipoproteinemia
- Familial mediterranean fever
- Hereditary angioneurotic edema
- Hemochromatosis

Endocrine

- Diabetic ketoacidosis
- Addisonian crises
- Hyperthyroidism
- ? Hyperparathyroidism

Inflammatory

- Noninfectious
  - Pancreatitis
  - Inflammatory bowel disease
- Infectious
  - Enteric infections (typhoid, shigellosis, staphyloccal enterocolitis, etc.)
  - Primary peritonitis (pneumococcal tuberculosis)
  - Pelvic inflammatory disease
  - Hepatitis (viral, Q fever, alcoholic)
  - Infectious mononucleosis
  - Herpes zoster
  - Pyelonephritis
  - Prostatitis
  - Nonspecific jejunitis (?)
  - Mesenteric adenitis (?)

Referred Pain

- Thoracic
  - Pericarditis
  - Pleuritis
  - Acute myocardial infarction
  - Myocarditis
- Abdominal wall (rectus sheath hematoma)
- Retroperitoneal
  - Renal colic
  - Renal infarction
- Neurologic
  - Tabes dorsalis
  - Nerve root compression
- Glaucoma
- Pelvic
  - Mittelschmerz
  - Endometriosis
- Abdominal migraine
- Abdominal epilepsy

Collagen Hypersensitivity

- Acute rheumatic fever
- Systemic lupus erythematosus
- Polyarteritis nodosa
- Henoch-Schoenlein purpura
- Allergy (?)

Drug-Toxin

- Heavy metals (lead, arsenic, mercury)
- Mushroom
- Staphylococcus toxin
- Arachnoidism
- Anticoagulants (especially coumadin)
- Narcotic withdrawal

Hematologic

- Sickle cell anemia
- Acute hemolytic states
- Leukemia
- Clotting abnormalities

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an overall range of 10 to 72 years).[2, 3] Attacks are precipitated by trauma, dental care, or physical or emotional stress in 54% of cases. Menstruation and oral contraceptives may induce attacks, but pregnancy and delivery have been associated with a decreased incidence. Patients obviously need to be prepared carefully for surgery or dental manipulations.

Recurrent abdominal pains occur in 93% of patients, are the presenting feature in 52%, and the major manifestations in 21%.[2, 3] Discomfort is usually moderate, vague, and diffuse without peritoneal signs, but intestinal obstruction and hypotension can occur. Nausea, vomiting and diarrhea are common, but fever is not. Submucosal edema of the bowel wall can yield a "stacked coin" appearance on x-ray.

Though even mild trauma can be a precipitating factor, the pain comes and leaves mysteriously, usually within 24 to 48 hours (range 4 hours to 1 week). Often several x-rays, including arteriograms, are ordered, and the patient sometimes is subjected to needless laparotomy. A normal CBC, absence of fever, and lack of localizing abdominal signs should allow conservative observation instead of surgery.

Deficiency of the inactivator of the first component of complement $\overline{C}_1$INH affects the kallikrein and fibrinolytic plasma symptoms as well as the complement cascade.[6] Thus these patients have played an important role in understanding the enzyme activities of these complicated systems. Nonetheless the pathophysiology of the episodic angioedema is not understood. It is known that during an attack of hereditary angioedema, unbridled C_1 persistently consumes C_2 and C_4 substrates which virtually disappear, while terminal components of the complement pathway remain in normal amounts. Both C_2 and C_4 can return to normal levels between episodic attacks, though C_4 usually remains diminished.[7]

A reasonable initial screen for hereditary angioedema is a C_4 level. Confirmation should include a protein $\overline{C}_1$INH level which is usually less than 30% normal. About 20% of patients will have normal $\overline{C}_1$INH *protein* levels, but abnormal *functional* $\overline{C}_1$INH levels in assays of enzyme activity. Systemic lupus erythematosus can also present with angioedema and a low C4 level and must be differentiated. Rarely an "acquired" $\overline{C}_1$INH deficiency exists in certain lymphoma patients.

Treatment consists of preventing attacks by stress modification and chronic androgen administration. The androgen derivative Danazol has been favored because it has fewer side effects than other androgens.[8] Danazol should be administered to patients with hereditary angioedema for at least 10 days before surgical operations or routine dental care. Fresh frozen plasma can also be given preoperatively to increase $\overline{C}_1$INH and C_4 levels. Antifibrinolytic agents have also been used as chronic preventive therapy.

No chemical maneuvers can shorten an ongoing acute attack. Tracheostomy is indicated if there is a sign of impending upper airway obstruction, including dysphasia or change in voice. Treatment of acute abdominal pain is symptomatic and supportive. Unnecessary tests should be avoided.

"Non-Surgical" Acute Abdomen

Certain important historical and physical clues should suggest the medical cause of an acute abdomen from the long list of possibilities shown in table 2. Nearly half the diagnoses are quite uncommon.[1] Nevertheless there are situations in which it is important to consider tests such as a thyroid panel, lipid panel, Watson-Schwartz urine test, heavy metal screen, drug urinary screen, stool white cells and red cells, $\overline{C}_1$INH assay, FANA, hemoglobin electrophoresis, etc.

The question of the cost effectiveness of an extensive work-up for uncommon disorders is a difficult one. Taking the time to listen to the patient and family and to do repeated physical exams should provide appropriate indications for individual tests. Acute abdominal pain is not an emergency, once bleeding and surgical causes have been ruled out. Careful observation could prevent costly, ineffective and unnecessary diagnostic x-rays, or even major surgery.

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SCIENTIFIC ARTICLE

Porphyria Cutanea Tarda in Association with Multiple Myeloma

Jon M. Maier, M.D. and Peter C. Ungaro, M.D.

• *Report of a patient with the previously undocumented association of porphyria cutanea tarda with multiple myeloma.*

PORPHYRIA cutanea tarda is the most common clinical abnormality of porphyrin metabolism.[1] The disease is characterized by hypertrichosis, hyperpigmentation, vesiculobullous dermatosis in sun exposed areas, and red-wine colored urine. It has occurred secondary to a variety of drugs, toxins, and diseases including various neoplasms. However, it has not been previously reported in association with multiple myeloma.

Report of a Case

T. H., a 65-year-old white female, presented with complaints of weakness and abdominal pain. She had been treated previously with methychlothiazide and deserpidine for hypertension, and she also had taken an iron-containing vitamin pill for six years for an "anemia." There was no history of ethanol ingestion, tobacco abuse, or other drug use. She denied exposure to hexachlorobenzene or other polychlorinated phenols. There was no family history of porphyria cutanea tarda. On physical exam she was obese and had hepatomegaly. Her complete blood count was remarkable for a normochromic normocytic anemia with a hemoglobin of 9.5 g/dl. The serum iron was 93 mg/dl with a TIBC of 240 mg/dl. Immunoelectrophoresis showed an IgG lambda monoclonal spike. A bone marrow aspirate and biopsy showed plasma cell infiltration.

Although therapy with melphalan and prednisone was initiated, the patient decided not to take additional cytotoxic therapy after the second four-day cycle, and it was ten months before she returned for further evaluation. She stated that her urine had been amber in color for the prior four months. She had persistent hepatomegaly, vesiculobullous dermatosis on the hands (figure 1) and face, hypertrichosis and hyperpigmentation on sun-exposed areas, and red-wine colored urine. A liver biopsy showed marked hepatic siderosis, and mild fibrosis. No mass lesion was seen on liver-spleen scan and serum ferritin was 1400 ng/ml. No serum antinuclear antibody was detected and the Watson-Schwartz test was negative. On a 24-hour urine collection uroporphyrins were 1200 mcg and coproporphyrins were 480 mcg. Analysis of another sample by high pressure liquid chromatography demonstrated the predominant porphyrins to be uroporphyrin and 7-carboxyl porphyrins. Fecal analysis showed a coproporphyrin level of 46 mcg/g and a uroporphyrin of 12 mcg/g. Erythrocyte uroporphyrinogen decarboxylase was normal.

The patient was kept away from sunlight and the skin lesions cleared over a period of two weeks. She refused chloroquine therapy and further treatment for her myeloma. Her anemia precluded phlebotomies.

Discussion

Several investigators have reported the association of porphyria cutanea tarda with tumors, primarily hepatic neoplasms including hepatic adenomas.[1] Resolution of the histological and biochemical evidence of porphyria cutanea tarda following removal of a tumor has been described.[2] Chronic myelocytic leukemia is the only hematologic neoplasm described with porphyria cutanea tarda to date.[3] The patient with chronic myelocytic leukemia, like ours, presented with signs of the underlying neoplasm and was treated with an alkylating agent, busulfan. Months later both that patient and our patient developed characteristic porphyria cutanea tarda. The patient with chronic myelocytic leukemia had hepatic leukemic infiltrates while ours had a liver biopsy that was remarkable primarily for the presence of siderosis. Increased hepatic iron stores are characteristically found in porphyria cutanea tarda,[4] and our patient's hepatic siderosis was an expected manifestation.

This paper reports the previously unreported association of porphyria cutanea tarda and multiple myeloma. It is possible that the simultaneous occurrence of these two disease processes was coincidental, but it is also quite possible that the myeloma may have induced the porphyria cutanea tarda. There are apparently two groups of patients with porphyria cutanea tarda in addition to the patients with hepatic neoplasms. One group has an inherited defect in uroporphyrinogen decarboxylase in both erythrocytes and hepatic cells.[5] The clinical syndrome becomes manifest when these patients are exposed to drugs or other chemicals that affect the porphyrin metabolic pathway. The other group consists of patients who have normal uroporphyrinogen decarboxylase levels in their erythrocytes. They seem to have selectively inhibited hepatic enzymatic activity from exposure to those few chemicals that are capable of producing this effect. It is possible that some of these

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From the Department of Medicine, New Hanover Memorial Hospital, Wilmington 28401.

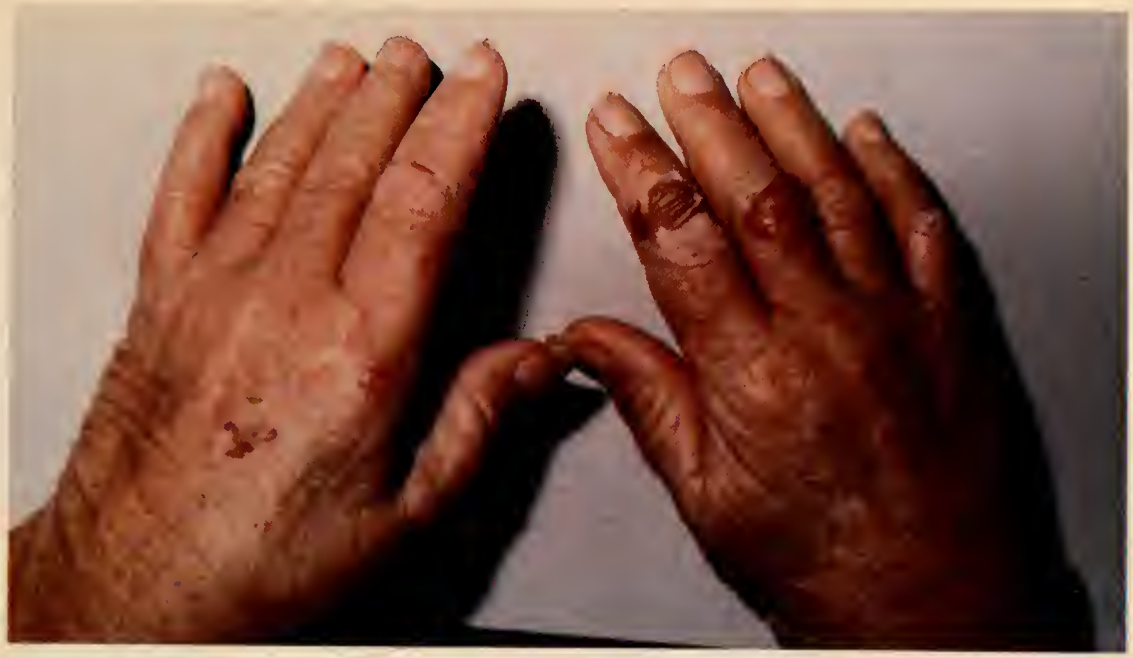

Figure 1. *Patient's vesiculobullous dermatosis.*

patients also have an inherited susceptibility due to some hepatic abnormality, but this has not been established. Our patient had normal erythrocyte enzyme levels and no history of exposure to chemicals associated with enzyme inhibition. It is possible that our patient's myeloma synthesized a substance that resulted in hepatic injury which caused a disruption of porphyrin metabolism. Further clinical observations in additional patients might clarify this issue.

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SCIENTIFIC ARTICLE

Chronic Myelogenous Leukemia Presenting Clinically As Diabetes Insipidus

Peter C. Ungaro, M.D., Jorge J. Gonzalez, M.D., Emile E. Werk, Jr., M.D., and J. Calvin MacKay, M.D.

• *Report of a patient in whom diabetes insipidus was the earliest clinical manifestation of chronic myelogenous leukemia.*

DIABETES insipidus is a rare complication of leukemia.[1] A careful review of the literature reported in 1971 identified 21 cases, of which only five were associated with chronic myelogenous leukemia.[2] Since that time several additional cases have been reported,[3] but most of these have been associated with acute leukemia. In the great majority of cases, the diabetes insipidus has become manifest after the diagnosis of leukemia has already been established. This report is about a case in which diabetes insipidus was the initial manifestation of chronic myelogenous leukemia. Possible mechanisms responsible for this presentation and therapeutic implications are emphasized.

Report of a Case

S.W. was referred to the Internal Medicine Service at New Hanover Memorial Hospital in January 1977 when she was 50 years of age. She had been in her usual state of good health until approximately two months prior to admission when she noted the gradual onset of increased thirst and water drinking associated with increased urinary volume and frequency. When she was evaluated by a neurologist a month prior to admission, she complained of lethargy related to sleep interruptions from having to get up every hour during the night to urinate. No neurological abnormality was detected then or subsequently.

On admission physical examination blood pressure was 164/94 and there was no lymphadenopathy or organomegaly. A complete blood count was as follows: hemoglobin 14.0 gm%, platelets 90,000, WBCs 35,100 with 37% polys, 13% bands, 5% metamyelocytes, 2% myelocytes, 32% monocytes, 1% basophils and 10% lymphocytes. Subsequent blood counts are indicated in table 1. Leukocyte alkaline phosphatase was normal. The vitamin B_{12} level was 1900 pg/ml. Bone marrow was hypercellular with a myeloid:erythroid ratio of 6.3:1. A subsequent bone marrow cytogenetic study was negative for the Philadelphia chromosome. No splenomegaly was found on liver-spleen scan.

Serum and urine osmolarities are shown in table 2. These are compatible with diabetes insipidus. There was a prompt rise in urine osmolarity with intramuscular administration of 10 units of vasopressin. Brain scan was within normal limits and skull films showed a normal pituitary fossa. The patient was discharged on lypressin nasal spray; no antileukemic therapy was begun.

In spite of the fact that the polyuria and polydipsia were well controlled, the patient was anxious for additional evaluation and was admitted to another hospital in June

Table 1
Treatment Profile

Date	Hgb	WBC × 10^3	Plts × 10^3	Therapy
Jan. 27, 1977	14.0	35.0	90	No treatment
June 30, 1978	12.2	51.8	102	Melphalan 4 mg daily started
July 28, 1978	12.7	13.6	86	Melphalan continued
Aug. 11, 1978	13.0	15.7	38	Treatment stopped (thrombocytopenia)
Oct. 10, 1978	13.4	7.4	41	No treatment
Nov. 17, 1978	12.6	16.3	65	No treatment
Feb. 2, 1979	13.3	29.9	77	Melphalan 2 mg every second day started
Mar. 16, 1979	12.9	18.8	70	Melphalan increased to 2 mg daily
April 6, 1979	9.7	21.6	84	Melphalan stopped (anemia)
June 1, 1979	10.7	16.9	66	No treatment
June 22, 1979	10.6	41.4	97	Melphalan restarted at 6 mg daily
July 2, 1979	8.8	12.8	90	Melphalan reduced to 4 mg daily
Aug. 10, 1979	10.2	25.0	89	Melphalan continued at 4 mg daily
Aug. 24, 1979	9.3	14.4	56	Melphalan stopped

From the Department of Medicine, New Hanover Memorial Hospital, Wilmington 28401.

Table 2
Vasopressin Stimulation and Water Deprivation Tests

	Urine Osmolarity	Serum Osmolarity
January 1977 Hospitalization		
Baseline	80	320
After vasopressin	580	320
June 1978 Hospitalization		
Baseline	90	320
After 16 hour water deprivation	170	360
After vasopressin	240	360

1978. A sixteen-hour water deprivation test was carried out followed by intramuscular administration of five units of vasopressin. The results are also shown in table 2. At that time her white blood cell count had risen to 94,600 with 20% polys, 31% bands, 11% metamyelocytes, 5% myelocytes, 13% lymphocytes and 19% monocytes. Splenic enlargement was now present on physical examination. No therapy for the leukemia was initiated. Desmopressin was substituted for lypressin with continued good control of the polyuria and polydipsia.

Because of the subsequent development of lethargy and malaise, chemotherapy with oral melphalan was started on June 22. She was treated with this drug intermittently as shown in table 1. Although the blood counts remained abnormal, treatment resulted in definite subjective improvement.

In March of 1979 the patient was admitted to the hospital for full mouth dental extraction for severely decayed teeth in association with a platelet count of 82,000. Simultaneous samples showed a serum osmolarity of 290 and a urine osmolarity of 130 after a twenty-four hour interruption of desmopressin therapy. A bone marrow carried out at this time showed 100% cellularity with 16% blasts and promyelocytes.

Subsequent to discharge the patient complained of progressively increasing malaise and lethargy, diffuse bone pain, and intermittent left upper quadrant pain with tenderness. The patient deteriorated rapidly and died in August 1979. No autopsy was performed.

Discussion

Diabetes insipidus is generally considered to be a rare disease, and its association with either primary or metastatic neoplasms is unusual. The tumor most frequently implicated in causing diabetes insipidus is metastatic breast cancer. In a review of thirty-nine patients with metastatic breast cancer and diabetes insipidus, it was found that in 27% diabetes insipidus was one of the initial manifestations that led to a diagnosis of recurrent disease.[4] However, the syndrome was always accompanied by the presence of other metastatic lesions, and the authors concluded that diabetes insipidus secondary to neurohypophyseal metastases occurred late in the course of the disease.

Although destruction of the posterior pituitary by metastases seems to be the mechanism producing diabetes insipidus in association with solid tumors, necrosis secondary to vascular occlusion can apparently cause diabetes insipidus in patients with leukemia.[2] Since no autopsy was obtained in the present patient, it is not possible to know if the diabetes insipidus was secondary to invasion by leukemic cells or to thrombosis from vascular occlusion. Factors against tumor involvement are the failure to develop additional hypothalamic or pituitary abnormalities during the initial eighteen months after diagnosis when she received no antileukemia therapy, the development of diabetes insipidus prior to evidence of additional organ infiltration such as splenomegaly or hepatomegaly, and the unchanging severity of the diabetes insipidus during the course of the leukemia, which included periods of both exacerbation and apparent control with chemotherapy. Although central nervous system dysfunction was apparent for several days immediately prior to the patient's death, infection, hemorrhage, or other factors could easily have been responsible for this. This is of some importance, since a course of cranial radiation therapy might be expected to benefit a patient with a leukemic cell mass, but would not be indicated if thrombosis were the cause.

Only two of the five adequately reported cases of chronic myelogenous leukemia in association with diabetes insipidus were autopsied, and both demonstrated leukemic infiltration of the pituitary.[2] In the only case reported in the English language literature, the leukemia was far advanced when the diabetes insipidus developed.[5] In other instances where diabetes insipidus has been found in association with leukemia, it has been noted that this is usually a late complication of the disease.[3] The patient reported in this paper is most unusual because of the rare association of diabetes insipidus with chronic myelogenous leukemia and because the diabetes insipidus was the earliest clinical manifestation, being present prior to the diagnosis of the leukemia.

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SCIENTIFIC ARTICLE

Solitary Thyroid Nodules in the Community Hospital: Use of the Percentage Cancer Index

Emile E. Werk, Jr., M.D., Barbara M. Vernon, BSN, RN-CFNP,
Jorge J. Gonzalez, M.D., Peter C. Ungaro, M.D., and Ralph C. McCoy, M.D.

• *This paper presents the results of a five year study of solitary thyroid nodules and suggests an algorithm for managing patients with such nodules.*

MANAGEMENT of solitary thyroid nodules continues to present a problem for the practicing physician. Although it is obviously important to detect and surgically treat cancer of the thyroid, it is also important to minimize unnecessary operations. Recently we reported on the operations for solitary thyroid nodules carried out in our community hospital during the three year period 1979 through 1981.[1] Cancer was found in 10 of 153 patients, giving a 6.5 percentage cancer index (PCI). The PCI is the percentage of operated patients in whom cancer is found.

Since then we have extended the survey for two additional years, 1982 and 1983, providing a total survey period of five years. Figure 1 shows the total thyroid and nodule operations performed, the PCI, and deaths due to thyroid cancer for each of the five years. From 1979 through 1982 the yearly thyroid and nodule operations ranged from 58 to 69 and 46 to 54, respectively. In 1983 there were unaccounted-for decreases to 39 and 29, respectively. Nevertheless the PCI fluctuated from 2 to 7.4 percent per year. The low PCI plus the fact that only 13 patients with thyroid cancer were found over five years in a community of over 250,000 persons supports current evidence that thyroid cancer is uncommon.

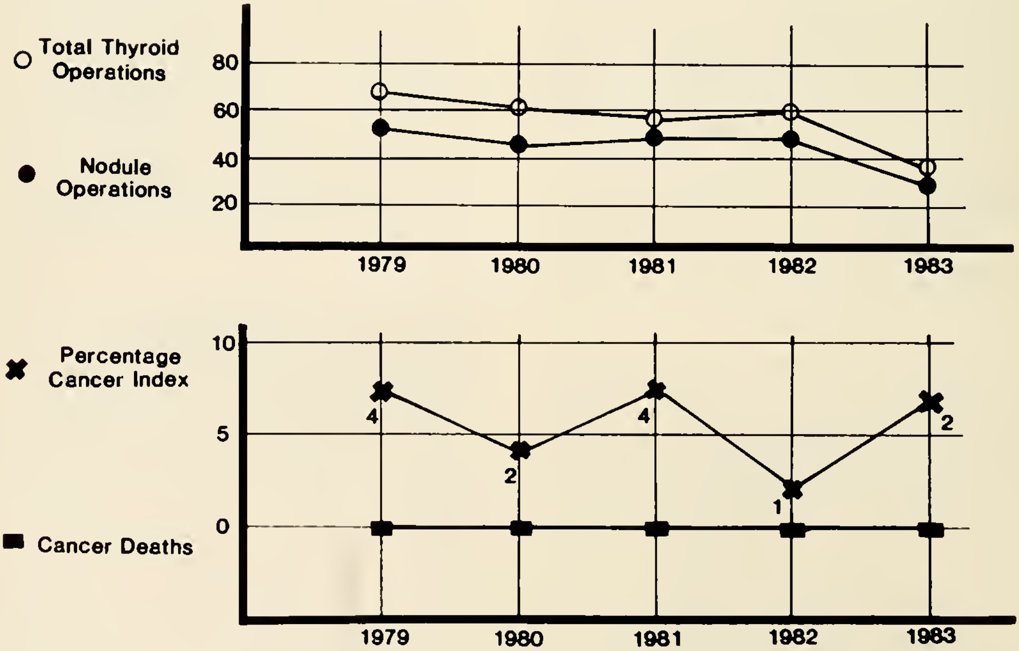

Figure 1. Total thyroid and nodule operations, percentage cancer index and cancer deaths for each year 1979 to 1983 at New Hanover Memorial Hospital. The numbers below the percentage cancer index line represent the actual numbers of cancer cases per year.

From the Departments of Medicine and Pathology, New Hanover Memorial Hospital, Wilmington 28401.

Table 1 shows demographic data for the 231 nodule operations. The largest number was performed in white women between the ages of 20 and 60. The prevalence of cancer according to sex, race and age is shown in table 2. The highest percentages of cancer were found in white women younger than 20 and in white men, suggesting that these groups have the highest risk. Table 3 shows the type and extent of cancer for the 13 patients. The overall PCI was 5.6%, 13 of 231 patients having cancer.

In our recently published report we reviewed the PCI in the medical literature over the last 38 years.[1] These data substantiate the usefulness of the PCI as a clinical index. It varies widely, depending on thoroughness of the preoperative evaluation. We separated the reports into three groups: In group 1, "all" patients with nodules went to surgery; in group 2, certain methods were employed to screen patients prior to surgery, e.g., clinical evaluation, radioactive iodine scan, sonogram and thyroid suppression; and in group 3, fine needle aspiration (FNA) was employed in addition to the screening methods in group 2. The PCI ranged considerably among the groups with the averages being 13.8%, 21.8% and 27.9%, respectively. Thus the PCI of 5.6% found in our survey would be considered low and indicates that many patients were operated on for the few patients found to have cancer.

Table 1
Demographic Data — Thyroid Nodule Operations, 1979-1983

	Ages				
	<20	20-40	40-60	>60	Total
Women					
White	9	65	63	19	156
Black	1	19	18	10	48
Men					
White	—	11	7	2	20
Black	—	2	3	2	7
Total	10	97	91	33	231

Table 2
Prevalence of Cancer in Thyroid Nodules, 1979-1983

	Ages			
	<20	20-40	40-60	>60
Women				
White	2/9 (22%)	3/65 (4.6%)	2/63 (3.2%)	—
Black	—	2/19 (10.5%)	—	1/10 (10%)
Men				
White	—	1/11 (9.1%)	1/7 (14.3%)	1/2 (50%)
Black	—	—	—	—

Table 3
Characteristics of Thyroid Cancer in 13 Patients, 1979-1983

Papillary Carcinoma — 11 Cases

2 patients — <1 cm
3 patients — 2 cm, 2 with capsular invasion
4 patients — 2 to 5 cm, 3 with invasion
2 patients — multifocal
2 patients with positive nodes

Follicular carcinoma — 2 patients
2 and 3 cm with invasion

How can the PCI be improved so that patients with cancer can be detected more accurately? The answer is multifactorial and requires a clear understanding of the many clinical and laboratory features involved. As shown in our survey, the highest risk groups are those persons less than 20 years of age, and white men. Various types of goiter are common in middle-aged white women, but this is the lowest cancer risk group. A history of definite recent growth and radiation therapy to the head and neck are well known high risk factors. A multinodular goiter or simply an enlargement of the contralateral lobe of the thyroid is usually a low risk finding for cancer. Serum measurements for thyrotropin to diagnose hypothyroidism and thyroid antibodies to diagnose Hashimoto's thyroditis are often helpful. Although papillary carcinoma can occur with Hashimoto's thyroiditis, this is a rare occurrence. Thyroxine for hypothyroidism and goiter suppression is the appropriate therapy for Hashimoto's thyroiditis. However if the nodule increases or a new nodule appears, cancer must be considered. The incidence of lymphoma, rarely associated with Hashimoto's thyroiditis as a large symptomatic nodule, may be increasing. It may be best diagnosed by needle biopsy prior to surgery, since radiation treatment may be indicated.[2] Triiodothyronine resin uptake values of serum should always be performed along with serum thyroxine levels to assess for an abnormality of thyroxine binding protein.

Perhaps the most confusing issue is that of a cold nodule found by isotopic scan. It must be emphasized that at least 85% of cold nodules are not cancer. Most are colloid nodules. A nodule showing decreased uptake (vs truly cold) is even less likely to be cancer. Actually the greatest use of a scan is to detect the functioning nodule, warm or hot, in which cancer is rarely found. Sonograms are helpful in delineating clinically suspicious cysts or mixed solid-cystic lesions.

If a trial of thyroid suppression is undertaken, an adequate dose of thyroxine, 0.2 to 0.3 mg daily, must be employed with regular follow-up exams. Preferably the thyrotropin level should be suppressed to less than 2.0 μU/ml and should not rise after thyrotropin stimulating hormone administration.

For the highest possible PCI at the lowest cost, FNA should be utilized.[3, 4] This technique has been slow to be employed in the community hospital setting because it has been stated that ten cases per week are needed to maintain adequate technical competence.[3] As more experience has accumulated, it has become apparent that aspiration can be performed by a properly trained physician whose experience is considerably more limited. The aspirate[5] or slide can be mailed for pathologic interpretation if sufficient expertise is not available locally. FNA of thyroid nodules has been considered by some investigators to have up to 95% accuracy with a 99% specificity and a 73% sensitivity.[3] A recent report, however, found false positive and false negative results of 24% and 9%, respectively.[6]

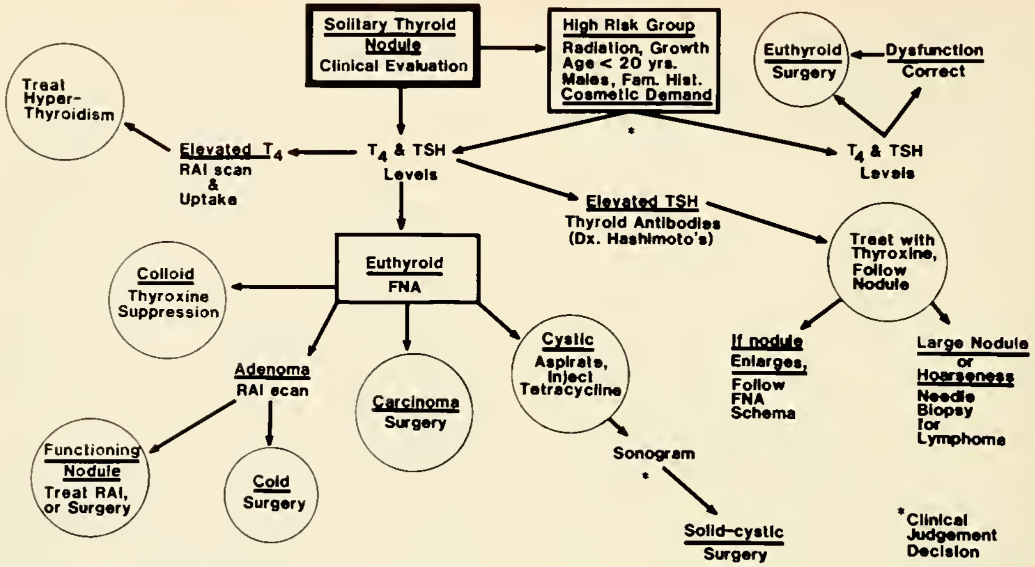

Figure 2. Algorithm for the management of solitary thyroid nodules in a community hospital setting. Abbreviations: FNA, fine needle aspiration; T$_4$*, thyroxine; TSH, thyrotropin; RAI, radioactive iodine.*

Utilizing FNA, the PCI of nodule operations should range from 50 to 78% in a standard clinical setting, even when some patients request nodule removal for cosmetic reasons or undue cancerphobia.

Based on the above considerations and the recommendations in the literature, we would currently suggest the algorithm outlined in figure 2 for managing thyroid nodules in a community hospital setting. This algorithm assigns FNA to a central role assuming that the appropriate expertise of aspiration, fixation and interpretation is available. The algorithm does not employ large needle aspiration, which is considered an important diagnostic step after FNA by some,[4] because considerable additional expertise is necessary.

Opposition to this algorithm might be raised because of a recently published decision analysis study which compared mortality and morbidity as end points for three treatment options for "cold" nodules. The options were 1) immediate surgery, 2) thyroxine suppression to select malignant nodules, and 3) FNA to determine the necessity of surgery.[7] Interestingly a significant difference was not found among the three options. Although this appears to be important information, it does not take into account several other clinical considerations such as the initial laboratory and radiologic studies needed for assessment of the solitary nodule, the time needed to make the diagnosis, patient acceptance, and cost. Nevertheless this analysis does indicate that if FNA is not available in a community, a radioactive iodine scan and sonogram could be substituted without affecting patient morbidity and mortality. Cold solid nodules could be managed by either immediate surgery or thyroxine suppression with surgery for nodules that do not regress. Patients with cytological results by FNA that were indeterminate or suspicious could be managed by either option. No matter which approach is employed, we believe that periodic review of the PCI should be helpful in following the success of local management. Finally, we must caution that no single algorithm will take into account all the clinical variables possible.[8] Clinical judgment is essential.

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North Carolina Medical Journal

Features for Patients October 1984

Some Useful Things to Know About the Heart

Norman J. Robinson, M.D.

Chest Pain

Chest pain causes concern since it is a common symptom of cardiovascular disease. There are a number of possible causes of chest pain, however, some serious and some not, which makes this a perplexing symptom for patients and physicians alike.

Cardiovascular disease is the leading cause of death in the Western world, causing approximately twice as many deaths as cancer. Coronary heart disease, which results from fatty deposits blocking the coronary arteries, is responsible for ninety percent of the deaths due to heart disease. Congenital heart disease, cardiac complications of high blood pressure, and rheumatic heart disease make up the other ten percent of cardiac deaths.

Coronary heart disease usually first manifests itself in one of three ways: angina pectoris, heart attack, or sudden death. **Angina pectoris** is the name given to recurrent chest pain or chest discomfort, usually during periods of activity. It is brought about by impaired oxygen supply to the heart muscle. This pain is usually experienced as a pressing or squeezing discomfort beneath the breast bone, and may be accompanied by a feeling of similar discomfort in the neck, jaw, arms or shoulders. It may take other forms, however, such as aching, pressure or choking, and sometimes a feeling of numbness in the arms and hands.

Heart attack is synonymous with **myocardial infarction,** and implies destruction of a portion of the heart muscle due to complete obstruction of one or more of the coronary arteries. A heart attack is usually accompanied by chest pain, somewhat similar to that of angina pectoris, but usually more severe. It is not usually related to activity, and frequently it is accompanied by other symptoms such as shortness of breath, sweating and nausea.

Sudden death may be the first manifestation of coronary heart disease, but it is often preceded by subtle symptoms which, if heeded, might lead to preventive action. Heart attack and sudden death are frequently heralded by new onset of angina pectoris, by worsening angina pectoris, or by development of anginal pain during non-stressful periods, such as during rest or sleep.

A sometimes confusing factor is that pain which is similar in location and which has the same characteristics as coronary heart disease can arise from other sources such as the esophagus, stomach, gall bladder, lungs, spine and chest wall. In addition, other types of cardiovascular problems may cause similar symptoms.

The circumstances in which the pain occurs may provide clues as to its source, such as whether it is brought on by physical effort, meals, swallowing, different types of movement, breathing, or lying in a particular position. Frequently there are many disorders that are capable of causing a patient's pain pattern. Often the cause can be found only by careful evaluation and consideration of all of the possibilities.

Since chest pain may arise from several sources, some potentially serious and some not, one should seek prompt medical attention when this symptom develops. Since fifty percent of deaths from heart attacks occur within two hours of the onset of symptoms, the importance of promptness cannot be overemphasized. Many of these deaths can be prevented if prompt medical attention is sought. Therefore, one should not ignore chest pain or wait for it to go away, but should seek evaluation in a physician's office or emergency room.

When evaluating chest pain, the physician will first attempt to define the nature of the pain by asking about its location, intensity, duration, the situation in which it developed, and other details about its characteristics. Evaluation will usually include a physical examination and an electrocardiogram. Additional laboratory and possibly x-ray tests may be required depending upon which sources of pain seem most likely after

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From the Department of Medicine, New Hanover Memorial Hospital, Wilmington 28401.

the initial examination.

More often than not, it will be determined that the patient's chest pain is not related to a cardiac problem, but is from a benign source which can be easily treated. On the other hand, if the pain is found to be due to heart disease, prompt attention may be life-saving.

If a potentially serious heart problem is suspected, precautions may be taken such as admitting the patient to the hospital and placing him/her on a heart monitor to determine if the chest pain is due to a heart attack or impending heart attack. This determination may require several days, and if the source of pain remains uncertain, additional testing may be required.

The electrocardiogram is a very important test which helps the physician decide on the likelihood of chest pain being due to heart disease. Since there are many variations of normal, comparison with a previous electrocardiogram on the same person provides valuable information. For this reason, it is wise to be sure of the availability of any old electrocardiograms for future comparison. A person who anticipates moving or traveling a great deal should carry a copy of a previous electrocardiogram.

Because of the complexities and potentially serious implications of chest pain, one should not feel reluctant or embarrassed about seeking prompt attention. A "prepare for the worst and hope for the best" approach is preferred since it may be life-saving as well as comforting.

CPR

Approximately 1.5 million Americans suffer heart attacks annually and about 40 percent of them die. Over half of the deaths take place outside of a hospital and occur within two hours after the onset of symptoms. These deaths are due to sudden cardiac arrest, usually resulting from severe irregularity of the heart. Thus, sudden death from coronary heart disease is our most important medical emergency.

Successful resuscitation is the only chance for survival for a substantial number of these patients whose deaths can be prevented by prompt, appropriate treatment and early entry into the emergency medical system. Victims of drowning, electrocution, suffocation, drug intoxication, and automobile accidents can often be saved by the same type of prompt resuscitation.

It has been almost twenty-five years since external chest compression was introduced, offering some hope for decreasing the more than 1000 sudden deaths that occur daily in the United States. In 1966, cardiopulmonary resuscitation (CPR) training was recommended for medical personnel, using standards established by the American Heart Association. In 1973, a National Conference on Standards for Cardiopulmonary Resuscitation and Emergency Cardiac Care, sponsored by the American Heart Association and the National Academy of Sciences/ National Research Council, recommended that

1. cardiopulmonary resuscitation training be extended to the general public;
2. training be in accordance with the standards of the American Heart Association;
3. certification for competency be based on nationally standardized curricula.

The American Red Cross, American Heart Association and other agencies were defined as providers of this training.

Since 1973, additional conferences, the latest by the American Heart Association in 1979, have modified the guidelines for training in CPR. Through these conferences, specific standards have been adapted for training and certification in basic life support (BLS) and advanced cardiac life support (ACLS). BLS training, in addition to teaching CPR through closed chest massage and artificial respiration, has been broadened to include recognition of symptoms of a heart attack, control of cardiac risk factors, management of victims of airway obstruction, and use of emergency medical services. This training is available to all lay people and is required of emergency medical personnel and most hospital personnel. ACLS involves the use of intravenous fluids, medications, mechanical ventilation, and electric heart shock, and is given as specialized training for paramedical and medical personnel.

Since training in CPR became available to large numbers of lay persons, along with development of rapid transport systems managed by well-trained paramedical personnel, survival from sudden death has improved substantially. Without prompt CPR by bystanders, however, successful resuscitation is less than half as likely despite the availability of a well-trained paramedical ambulance team. Thus, the role of the lay bystander is indispensible to successful resuscitation of the cardiac arrest victim.

It has been estimated that a well-trained lay public, along with a well-developed emergency cardiac care system, may save between 100,000 and 200,000 lives annually in the United States. As many as 43 percent can survive cardiac arrest due to heart rhythm disturbances if BLS is begun by trained persons within four minutes of the arrest and a transport team trained in ACLS arrives within eight minutes of the arrest. This makes it clear that the community at large is the "ultimate coronary care unit."

Whereas BLS training is valuable for anyone, it may be of particular importance to individuals who work with large groups of people or who live or work with people who have or are predisposed to cardiovascular disease. Training and certification in BLS may be arranged through local American Red Cross and American Heart Association chapters. These programs use standardized training and testing methods. Persons interested in maintaining certification must be retested annually.

The "model" system of complete emergency cardiac care must include basic life support, advanced cardiac life support and an efficient transport service. Basic life support is the holding action which will maintain effective circulation and respiration for a limited period of time until advanced cardiac life support and transportation are available. In communities with large numbers of lay persons trained in BLS and with a rapid response system of trained ACLS personnel, large numbers of sudden death victims have been saved.

Palpitations

The word **palpitation** is derived from the latin word **palpitare** which means "to throb." It is used to describe an awareness of heart action such as feeling of the heart beating irregularly or faster or more forcefully than usual.

Awareness of the heart beat commonly occurs when the heart rate increases in response to normal stimuli such as exercise, excitement, or fright. In addition, many people occasionally experience a feeling of skipping or "flip-flopping" of the heart due to premature beats. When these occur accosionally in a healthy individual who is free of other symptoms, they are generally felt to be benign.

In contrast, palpitations that are not provoked by anxiety, that occur frequently, or that are associated with other symptoms such as chest pain, shortness of breath, dizziness, or spells of passing out, may indicate significant disturbances of heart rhythm which require evaluation and therapy. Such disturbances may be due to heart disease or may be secondary to some other illness such as anemia, excessive thyroid function, or infection. Additionally, such disturbances may be due to excessive stimulation of the heart by such things as caffee, tea, tobacco, or drugs. Emotional disturbances may also be responsible for excessive awareness of heart action.

Persons experiencing palpitations should take careful note of the circumstances in which they occur and, in particular, any relationship to time of day, excitement, stress, physical activity, and stimulant beverages. Additionally, careful note should be taken of other associated symptoms. This kind of information is valuable to the physician's understanding of the symptom.

Persons who consult their physician because of palpitations usually require careful questioning as well as a physical examination. An electrocardiogram and other laboratory tests are usually included in the evaluation. If these do not provide sufficient information, additional testing, such as a treadmill stress test and a 24-hour tape recording of the patient's electrocardiogram while he is engaging in normal activities, may be considered. The purpose of the evaluation is to confirm the presence of a heart rhythm disturbance, to determine its type, and to detect any association with heart disease or other illness.

Once the cause of palpitations is understood, judgment can be made as to the implications and need for therapy. Generally, physicians will tailor the aggressiveness of their evaluation and therapy to the severity of the patient's symptoms and the seriousness of any underlying illness. Therapy may range from reassurance to intensive medical therapy. In all instances, therapy is intended to reduce symptoms, to alleviate or control underlying conditions, or to prevent development of more serious problems.

Hair Today, Gone Tomorrow — Alopecia

Russell W. Eyre, M.D., Claude S. Burton, M.D. and J. Lamar Callaway, M.D.

Baldness has been considered a curse since early recorded history. Isaiah, in the Old Testament, warned that all the hair would be removed from the daughters of Zion because of their wickedness. Julius Caesar tried to camouflage his balding scalp by combing his hair forward. A full head of hair has been considered a mark of youth and beauty.

All mammals have hair. Most have a thick coat over their entire body to protect them from the elements. Man has most of his body covered with fine lanugo hairs. Long terminal hairs are present on the scalp. The only spots normally hairless are the palms and soles. In the developing fetus hair begins to grow early, within the first three to four months after conception. This fine lanugo hair is shed about one month before birth. The second coat of hair is then shed within the first year of life. Cycles of shedding and growth continue throughout our lives, but the cycles are not coordinated after the first few.

Each hair has a growth phase called anagen. The length of this growth phase determines how long a hair will grow. Hair grows about one inch every two months. To grow a hair one foot long would take an anagen phase of two years. Most anagen phases last about three years. The resting phase of a hair is called telogen. This phase usually lasts three months. The transition between a growing and resting hair is called catagen.

Nine out of every ten hairs are in anagen phase. A hair is shed when a follicle holding a resting hair begins to form a new hair. This new anagen hair pushes the telogen hair out of the follicle. About one hundred hairs are shed this way every day. Hairs are dead once they emerge from the follicle. The only living portion of a hair is buried deep in the skin. The normal density of hair is one thousand hairs per square inch. Half of the hairs in one area may be lost before it becomes noticeably thin. The normal scalp has about one hundred thousand hairs and this may weigh from four to ten ounces, depending on the length.

There are many types of hair loss. Two general categories are those that produce scarring in the hair follicle and those that don't damage the follicle. Alopecia or baldness that is caused by scarring is often produced by an infection of the hair follicle but may also be caused by burns, radiation or skin cancers. There are no follicles left to regrow hair in those areas. However, non-scarring alopecias merely have long terminal hairs replaced by short fine lanugo hairs. Occasionally these fine lanugo hairs may begin to produce long terminal hairs again. The non-scarring alopecias can be subdivided into those producing localized and those producing generalized hair loss. Generalized hair loss is usually caused by a toxic effect on the hair root. Severe illness with high fevers, vitamin deficiencies, endocrine diseases, pregnancy, cancer chemotherapy and various poisons may all cause this toxic diffuse alopecia. Non-scarring localized alopecia is usually either alopecia areata or male pattern baldness.

Alopecia areata usually occurs in patients younger than twenty-five. Patches of scalp hair fall out almost overnight. The beard, eyebrows, eyelashes, and pubic hair may also be affected. The growing cycle is abruptly stopped and many anagen hairs change to telogen hairs. These hairs are weak and break off easily. The root of the hair is surrounded by cells that usually fight infection. These cells appear to put the follicle to sleep. The cause of alopecia areata is unknown, but many patients regrow their hair within several months or years.

Male pattern or common baldness affects eighty percent of all males by eighty years of age. In one out of twenty males some form of common baldness is seen before age twenty. It is so frequently seen that it should be considered a normal part of aging. Hair loss occurs in distinct patterns, beginning with frontal recession and progressing to loss over the entire top of the head leaving only a small ring of normal hairs at the lower portion of the scalp. The follicles in the bald area have stopped producing terminal hairs. Only fine soft short lanugo hairs are present.

Occasionally women with tumors that produce male hormones have male baldness. Eunuchs — men who were castrated before puberty — never develop male pattern baldness. It is obvious that this "normal" feature of aging, common baldness, is hormonally related. However the precise mechanism of this hormonal action is unknown. Genetics and age also play a role. Baldness is rare in some races, especially in the Indian and Oriental races. Local factors such as hair style, frequency of hair cuts, and the wearing of hats do not influence the course of male pattern alopecia.

The cause of the alopecia must be determined before treatment is started. If the alopecia is non-scarring there is a possibility of hair regrowth when the cause is removed. Toxins, severe illness or endocrine imbalances are usually evident from other symptoms. Alopecia areata may respond to treatments that affect a localized immune response such as steroids, light treatments, irritants, or allergens. Almost every cream ever formulated has been touted by someone to help regrow male pattern hair loss. Until recently all those claims have been unfounded.

Ten years ago a powerful new drug used to treat high blood pressure was noticed to change fine, soft lanugo hairs to darker, longer, terminal hairs. This change was very disturbing especially when it occurred on the face of young children. When this drug, Minoxidil, was put into a lotion it restored the frontal hair loss seen in some apes. Clinical trials in humans are currently in progress. Many questions remain unanswered about the topical use of this medication, and the Federal Drug Enforcement Agency has not approved its topical use. The dermatologic clinical trials unit at Duke University Medical Center is participating with a number of other medical centers in studies directed at answering those remaining questions.

When skin containing long terminal hairs is transplanted to areas containing lanugo hairs the terminal hairs do not change their appearance. In male pattern baldness, the technique of transplanting hair from the ring of normal hair along the lower scalp to the top of the scalp has grown into a multimillion dollar business. Excising a portion of bald scalp may be combined with hair transplants to produce a satisfactory result. However the procedure is expensive, painful, and not without hazards.

The judicious use of a wig or hair piece can be the easiest and least expensive approach to solving the curse of alopecia.

LEARNING WITHOUT WORDS

You Better Look Behind the Ears

Jorge J. Gonzalez, M.D.

- *Mysterious loss of thirty pounds by an elderly woman is explained by looking behind her ears.*

NOT long ago, a 71-year-old woman was referred to our university clinic for the evaluation of severe weight loss (30 lb) over the preceding three months. She had had a left middle ear infection three months previously, associated with vertigo and some nausea. She was treated with antibiotics, and a myringotomy tube was placed. After this episode, her appetite decreased markedly, and she lost her taste for food. She felt that after chewing food for a few seconds, the food grew into a "big tasteless wad," and she could not swallow it. An attempt to elucidate the cause of her weight loss resulted in an extensive radiological and biochemical evaluation which was negative.

Her review of systems was noncontributory. Her past medical history was remarkable only for mild hypertension for which she was taking a thiazide diuretic. She denied the use of any other medications.

Physical examination revealed an emaciated female in no acute distress. The only positive findings were the presence of a transdermal scopolamine patch (Transderm V) in the left retro-auricular area and an extremely dry buccal mucosa. On questioning, the patient stated that she had been using the patches every three days. They had been prescribed for the relief of vertigo and nausea, and they had been extremely successful in doing this. After stopping using the patches, the patient developed a voracious appetite, and rapid weight gain ensued.

The inhibition of salivary secretions by antimuscarinics is well known. In this case the chronic use of low dose scopolamine via transdermal absorption apparently produced marked weight loss by interfering with salivary secretion. It is remarkable that no other antimuscarinic side effects were evident.

In these days of improved drug delivery systems, one needs to carefully explore every inch of skin before embarking on an extensive workup. Possibly induction of Sjogren's syndrome with transdermal scopolamine is warranted in some cases of morbid obesity.

From the Department of Medicine, New Hanover Memorial Hospital, Wilmington 28401.

LEARNING WITHOUT WORDS

The History That Wasn't

Norman J. Robinson, M.D.

• *A middle-aged man with a "heart condition" is restored to complete health, and the value of history taking is underscored again.*

IT all seemed pretty straightforward. The fifty-year-old moderately rotund man had recently moved to our quiet beach community after escaping from the hectic life of a business executive. To occupy himself and keep food on the table, he had purchased a small motel.

He came, complete with bottles of Isordil and nitroglycerine, to find a new doctor for his "heart condition." He told of having been hospitalized several months previously with an episode of severe chest pain. Since then, he had had repeated milder episodes of pain, always relieved promptly by nitroglycerine. He felt that he was doing reasonably well and wished to keep medical expenses to a minimum since he had not yet replaced his medical insurance and knew that his condition would bring with it a fearful policy premium. He did consent to an electrocardiogram which revealed nonspecific ST-T changes.

After several months of doing well, he returned in the midst of the tourist season to report worsening chest pain. "I can hardly do anything without getting chest pain," he said. "Why, I can't even make it across my motel parking lot without stopping to take a nitroglycerine tablet." (Still no medical insurance.) Sounds pretty bad, I thought. After some debate over how best to approach the problem he consented to taking more medicine — bigger Isordil tablets and a beta blocker.

Within several days, his symptoms were much better and the motel business was thriving. A couple of months later, however, he presented again with worsening chest pain. "Why, I can't even walk across my motel parking lot without having to stop to take a nitroglycerine tablet." (Still no medical insurance.) Things are getting worse, I thought. After some discussion, he consented to more medication — nitrates plus a bigger beta blocker. Within a few days, his symptoms were much improved.

Several months later, my patient returned to report a strange and marvelous occurrence. He had made a trip to London to attend a friend's funeral. On the airplane crossing the Atlantic Ocean, he was suddenly seized by crushing chest pain and discovered, to his horror, he had left his nitroglycerine tablets at home. The stewardess, wishing to avert a calamity and having little else to offer, gave him a hefty dose of Maalox. Miraculous, immediate and complete relief of his pain ensued. "Now I get quicker relief with Maalox than with nitroglycerine, even when I walk across my motel parking lot," he exclaimed. I quickly came to the obvious conclusion: "something's not quite right." He consented to some tests. On the treadmill, he had the endurance of an Olympic athlete and had no chest pain or ischemic changes. His upper GI series revealed a substantial hiatal hernia, gastroesophageal reflux and esophageal spasm. An antireflux regimen eliminated all of his symptoms and his cardiac medicines were stopped.

Still bewildered by the entire situation, I felt compelled to resort to a basic technique: history taking. "Tell me more about walking across the motel parking lot. What does that involve?" "Well," he said, "I frequently walk across the parking lot to check the rooms. Since my guests dump trash out of their cars onto my parking lot, I usually bend over to pick up trash as I go. Come to think of it, that's when I get the chest pain."

From the Department of Medicine, New Hanover Memorial Hospital, Wilmington 28401.

LEARNING WITHOUT WORDS

“Tips” on Acute Arthritis and Clubbing

Nancy B. Allen, M.D.

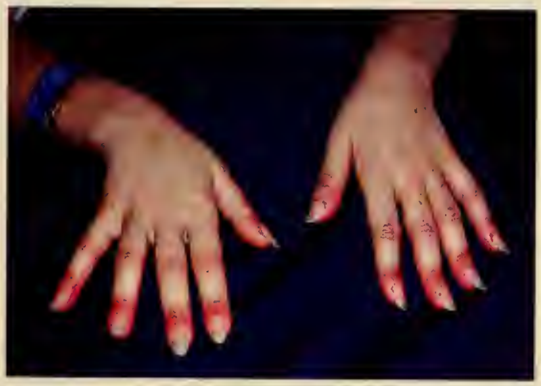
• *Two color photos beautifully illustrate the painful effects of hypertrophic osteoarthropathy in a patient whose endometrial cancer had metastasized to a lung.*

As physicians, we must always pay attention to the patient. New symptoms or signs usually mean something. This is especially true in a patient with cancer, as you will see in this report.

A 50-year-old woman was hospitalized with fever, cough, joint pains and painful enlargement of her fingertips and toes. She had been well until 22 months previously when she underwent hysterectomy for excessive bleeding. A small and apparently incidental endometrial carcinoma, not involving the myometrium, was discovered; no further therapy was deemed necessary. Sixteen months after surgery she began complaining of pain in the region of the coccyx, eventually with weight loss and constipation. Rectal examination revealed a 2 cm mass along the left pelvic sidewall. A second operation was performed and this mass was found to be metastatic adenosquamous carcinoma, with all nodes negative. Postoperative local radiation with 4500 Rads was administered.

One to two weeks before admission, she noted gradual worsening of fever, dry cough, further weight loss, anorexia, and pain of the wrists, small hand joints, knees, ankles and toes. On admission, her temperature was 38.5° and there was prominent clubbing of fingers and toes, symmetrical polyarthritis involving distal joints (figure 1), and tenderness along both distal tibias. Lung examination was normal.

Laboratory results were nonspecific, with hematocrit 34%, normal white blood count, platelet count 611,000. Chest x-ray (figure 2) showed a solitary, 1.5 cm pulmonary nodule in the right lower lobe. Thin needle aspirate of this nodule showed adenosquamous carcinoma. Radiographs



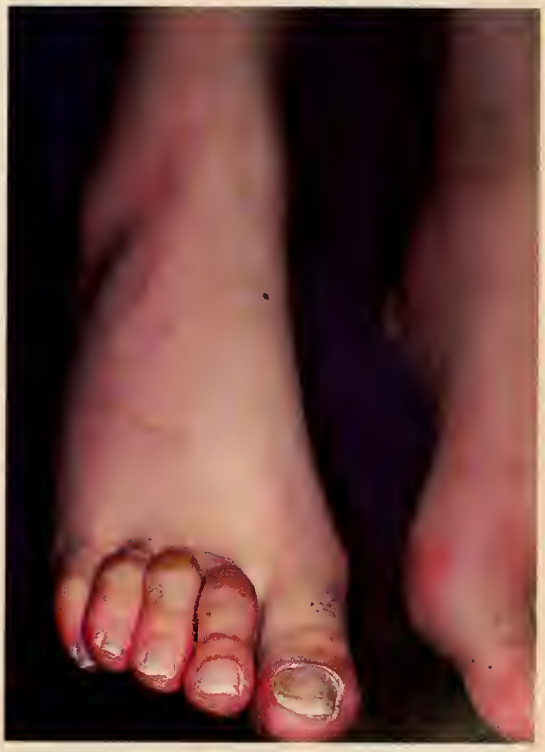


Figure 1. *Fingers, toes and right ankle showing joint swelling and clubbing.*

From the Department of Medicine, Duke University Medical Center, Durham 27710.

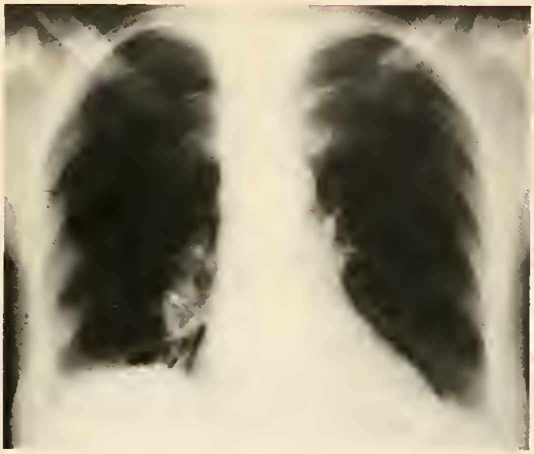


Figure 2. *Chest radiograph with peripheral 1.5 cm right pulmonary nodule overlying rib.*

of the hands and feet (figures 3 and 4) showed typical changes of hypertrophic osteoarthropathy.

The patient's pain and fever did not respond to antibiotics, fluids, and acetaminophen. We saw her and suggested treatment with ibuprofen 600 mg QID. Within 24 hours her temperature decreased and her joint symptoms improved markedly. Direct cancer therapy with cis-Platinum and radiation to the lung and mediastinum led to continued improvement in the clubbing and arthritis, even when ibuprofen was stopped. However, she died of progressive metastatic cancer six months later.

Discussion

This patient developed clubbing and arthritis simultaneously with the discovery that her endometrial carcinoma had metastasized to the lung. Hypertrophic osteoarthropathy (HOA), or hypertrophic pulmonary osteoarthropathy as this syndrome was called previously, occurs in the setting of a variety of pulmonary and extrapulmonary conditions. The former include primary or metastatic neoplasms, infections (empyema, bronchiectasis, lung abscess, tuberculosis), cystic fibrosis, and bronchogenic cysts. Extrapulmonary conditions associated with the development of HOA include bacterial endocarditis, gastrointestinal infections, cirrhosis, inflammatory bowel disease, endocrine disorders, and neoplasms (gastrointestinal, renal, lymphoma, chronic myelogenous leukemia).

The classic triad of hypertrophic osteoarthropathy is arthritis, periostitis and clubbing. The arthritis generally involves the wrists, hands, knees, ankles, and feet and may mimic rheumatoid arthritis. It is often very painful and accompanied by fever as in our patient. The periostitis causes distal long bone pain of varying severity, which is increased by dependency and relieved by elevation. The description of clubbing dates back to Hippocrates in 400 B.C. who described softening and accentuated convexity of the nail and loss of the normal 15° angle between nail and nailbed. Local warmth, swelling and erythema may be seen as in the photographs of our patient. Physical examination

Figure 3. *Proximal phalanx of finger showing fluffy periostitis.*

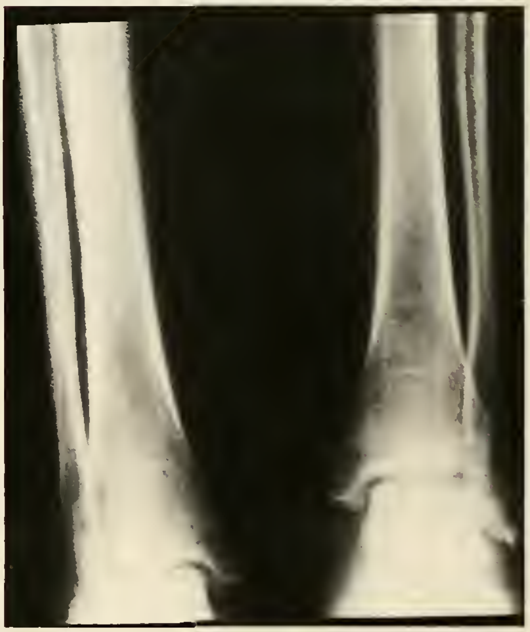


Figure 4. *Distal lower extremities with prominent soft tissue swelling and periostitis.*

reveals symmetrical clubbing in fingers and toes. Edema occurs in the hands and feet; warmth, tenderness and less often redness are noted over the feet, legs, and forearms. The skin may appear shiny. Symptomatic joints often show effusions and limited motion.

Epidemiologically, HOA affects men and women equally. Age distribution reflects that of the underlying disorder. The erythrocyte sedimentation rate may be elevated, but no specific tests are available for diagnosis. Synovial fluid is generally non-inflammatory.

Radiographic findings consist of periosteal thickening along the long and short bones. Initially there is a thin, continuous, sclerotic line separated from the bony cortex by a narrow lucent line; later, this periosteal new bone formation thickens and fuses with the cortex. Osteoporosis may appear in later stages. These changes are seen in the tibia, fibula, radius, ulna and later in hands and feet along phalanges. Bone scan demonstrates characteristic linear uptake along these bones and around affected joints.

Etiology of HOA remains speculative. Vagal stimulation, hypervascularity as a response to ischemia, local circulatory abnormalities, hormonal changes (elevated growth hormone, estrogen), tumor immune complexes, and prostaglandins have all been suggested to play a role. It is intriguing that the onset of our patient's HOA coincided with the development of pulmonary metastases from her endometrial adenosquamous cancer.

The most effective treatment of HOA is to treat the underlying condition. If that is tumor, as in the case presented here, surgical, chemotherapeutic or radiation therapy should be employed without delay. Anti-inflammatory drugs such as aspirin, ibuprofen, indomethacin, or corticosteroids, are often effective in reducing symptoms related to HOA. The course varies greatly, but dramatic relief has been described in the recovery room following removal of a primary lung cancer. Certainly our patient responded within 24 hours of beginning ibuprofen.

HOA is a triad of arthritis, periostitis and clubbing and in its typical form should alert the physician to search for an underlying or primary condition. Our patient's HOA acted as a marker for recurrent endometrial cancer, and was temporally related to pulmonary metastases and not to her primary or locally recurrent disease. Treatment with ibuprofen and subsequently with chemotherapy and radiation therapy substantially reduced her joint symptoms.

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Programs: Adult and Adolescent Addictive Disease

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Please turn the page for a brief summary of prescribing information.

Motrin® 400 & 600 mg TABLETS
ibuprofen

Good medicine...good value

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Motrin® Tablets (ibuprofen)

Contraindications: Anaphylactoid reactions have occurred in individuals hypersensitive to *Motrin* Tablets or with the syndrome of nasal polyps, angioedema and bronchospastic reactivity to aspirin, iodides, or other nonsteroidal anti-inflammatory agents

Warnings: Peptic ulceration and GI bleeding, sometimes severe, have been reported Ulceration, perforation and bleeding may end fatally An association has not been established Use *Motrin* Tablets under close supervision in patients with a history of upper gastrointestinal tract disease, after consulting ADVERSE REACTIONS In patients with active peptic ulcer and active rheumatoid arthritis, try nonulcerogenic drugs, such as gold If *Motrin* Tablets are used, observe the patient closely for signs of ulcer perforation or GI bleeding

Chronic studies in rats and monkeys have shown mild renal toxicity with papillary edema and necrosis Renal papillary necrosis has rarely been shown in humans treated with *Motrin* Tablets

Precautions: Blurred and/or diminished vision, scotomata and/or changes in color vision have been reported If these develop, discontinue *Motrin* Tablets and the patient should have an ophthalmologic examination, including central visual fields and color vision testing

Fluid retention and edema have been associated with *Motrin* Tablets, use with caution in patients with a history of cardiac decompensation or hypertension In patients with renal impairment, reduced dosage may be necessary Prospective studies of *Motrin* Tablets safety in patients with chronic renal failure have not been done

Motrin Tablets can inhibit **platelet aggregation** and prolong bleeding time Use with caution in persons with intrinsic coagulation defects and on anticoagulant therapy

Patients should report signs or symptoms of **gastrointestinal ulceration** or bleeding skin rash, weight gain, or edema

Patients on prolonged **corticosteroid therapy** should have therapy tapered slowly when *Motrin* Tablets are added

The antipyretic, anti-inflammatory activity of *Motrin* Tablets may mask inflammation and fever

As with other nonsteroidal anti-inflammatory drugs, borderline elevations of liver tests may occur in up to 15% of patients These abnormalities may progress, may remain essentially unchanged, or may be transient with continued therapy Meaningful elevations of SGPT or SGDT (AST) occurred in controlled clinical trials in less than 1% of patients Severe hepatic reactions, including jaundice and cases of fatal hepatitis, have been reported with ibuprofen as with other nonsteroidal anti-inflammatory drugs If liver disease develops or if systemic manifestations occur (e g eosinophilia, rash, etc.), *Motrin* should be discontinued

Drug interactions. *Aspirin* used concomitantly may decrease *Motrin* blood levels

Coumarin bleeding has been reported in patients taking *Motrin* and coumarin

Pregnancy and nursing mothers: *Motrin* should not be taken during pregnancy or by nursing mothers

Adverse Reactions: The most frequent type of adverse reaction occurring with *Motrin* is gastrointestinal of which one or more occurred in 4% to 16% of the patients

Incidence Greater than 1% (but less than 3%)—Probable Causal Relationship

Gastrointestinal: Nausea,* epigastric pain,* heartburn,* diarrhea abdominal distress, nausea and vomiting, indigestion, constipation, abdominal cramps or pain, fullness of GI tract (bloating and flatulence), **Central Nervous System:** Dizziness,* headache, nervousness. **Dermatologic:** Rash* (including maculopapular type), pruritus, **Special Senses:** Tinnitus, **Metabolic/Endocrine:** Decreased appetite, **Cardiovascular:** Edema, fluid retention (generally responds promptly to drug discontinuation, see PRECAUTIONS)

Incidence less than 1%—Probable Causal Relationship**

Gastrointestinal: Gastric or duodenal ulcer with bleeding and/or perforation, gastrointestinal hemorrhage, melena gastritis, hepatitis, jaundice, abnormal liver function tests, **Central Nervous System:** Depression, insomnia confusion, emotional lability, somnolence, aseptic meningitis with fever and coma **Dermatologic:** Vesiculobullous eruptions, urticaria, erythema multiforme, Stevens-Johnson syndrome alopecia, **Special Senses:** Hearing loss, amblyopia (blurred and/or diminished vision, scotomata, and/or changes in color vision) (see PRECAUTIONS), **Hematologic:** Neutropenia, agranulocytosis, aplastic anemia, hemolytic anemia (sometimes Coombs positive), thrombocytopenia with or without purpura, eosinophilia, decreases in hemoglobin and hematocrit, **Cardiovascular:** Congestive heart failure in patients with marginal cardiac function, elevated blood pressure, palpitations, **Allergic:** Syndrome of abdominal pain, fever, chills, nausea and vomiting; anaphylaxis, bronchospasm (see CONTRAINDICATIONS), **Renal:** Acute renal failure in patients with pre-existing significantly impaired renal function, decreased creatinine clearance, polyuria, azotemia, cystitis, hematuria **Miscellaneous:** Dry eyes and mouth, gingival ulcer, rhinitis

Incidence less than 1%—Causal Relationship Unknown**

Gastrointestinal: Pancreatitis, **Central Nervous System:** Paresthesias, hallucinations, dream abnormalities, pseudotumor cerebri, **Dermatologic:** Toxic epidermal necrolysis, photoallergic skin reactions, **Special Senses:** Conjunctivitis, diplopia, optic neuritis, **Hematologic:** Bleeding episodes (e g epistaxis, menorrhagia), **Metabolic/Endocrine:** Gynecomastia, hypoglycemic reaction, **Cardiovascular:** Arrhythmias (sinus tachycardia sinus bradycardia); **Allergic:** Serum sickness, lupus erythematosus syndrome, Henoch-Schonlein vasculitis, **Renal:** Renal papillary necrosis

*Reactions occurring in 3% to 9% of patients treated with *Motrin* (Those reactions occurring in less than 3% of the patients are unmarked)

**Reactions are classified under "*Probable Causal Relationship (PCR)*" if there has been one positive rechallenge or if three or more cases occur which might be causally related Reactions are classified under "*Causal Relationship Unknown*" if seven or more events have been reported but the criteria for PCR have not been met

Overdosage: In cases of acute overdosage, the stomach should be emptied The drug is acidic and excreted in the urine so alkaline diuresis may be beneficial

Dosage and Administration: Rheumatoid arthritis and osteoarthritis Suggested dosage is 300, 400, or 600 mg t.i.d or q.i.d Do not exceed 2400 mg per day Mild to moderate pain 400 mg every 4 to 6 hours as necessary

Caution: Federal law prohibits dispensing without prescription. MED B 7 S

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Upjohn The Upjohn Company
Kalamazoo, Michigan 49001

J 4791 August 1984

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MEDICAL EDUCATION

Practice Patterns of Graduates of a North Carolina Community Hospital Internal Medicine Training Program

Peter C. Ungaro, M.D. and Jorge J. Gonzalez, M.D.

- *One answer to the question, Are AHEC's aims being accomplished?*

THE Area Health Education Center (AHEC) program of the University of North Carolina established primary care residency training positions in various community hospitals in the state. One of the objectives was to expose residents and students to high quality community hospital experiences. It was thought that a satisfactory experience in an institution remote from the university center would induce trainees to settle in areas of the state that had inadequate numbers of physicians. At the same time the presence of the training programs would stimulate continuing medical education and improve the quality of care in community hospitals, increasing their attractiveness to prospective practitioners.

The internal medicine training program at New Hanover Memorial Hospital in Wilmington was initiated in 1972. The hospital is a community institution serving the southeastern coastal area, currently with 468 operational beds. Five medical school graduates began residencies at the first year level in 1973. The first trainees to complete the full three years of postgraduate training required for board eligibility graduated in 1976. This report describes the locations and types of practices that the program graduates have selected.

In the last several years information has been published describing the career choices of graduates of internal medicine training programs.[1, 2] This report in part concerns itself with the contrast between graduates of the training program at New Hanover Memorial Hospital and the national experience.

Resident Data

In the seven-year period from 1976 through 1982 twenty-three residents completed a full three years of training in internal medicine at New Hanover Memorial Hospital. Of these, fifteen went into practice in North Carolina. Seventeen were graduates of American medical schools and six were graduates of foreign medical schools. One of the foreign graduates was an American citizen. Table 1 compares numbers of American and foreign graduates who entered practice in North Carolina. The foreign graduates were more likely to remain in the state. Table 1 also contrasts those who graduated from out-of-state American medical schools with those who graduated from North Carolina schools. All six of the North Carolina graduates went into practice in North Carolina, while only four of the eleven out-of-state graduates entered practice in this state. For the out-of-state American graduates, proximity to North Carolina had some impact. Adjacent states were considered to be South Carolina, Kentucky, Tennessee, Virginia, and West Virginia. Graduates of medical schools in these states were more likely to remain in North Carolina or the adjoining states as shown in table 2.

Practice patterns within the state demonstrate less clear differences as shown in tables 3 and 4. Foreign medical graduates were the most prone to practice near Wilmington. The seven graduates electing to practice in North Carolina towns of less than 30,000 were fairly evenly divided when compared on the basis of where they went to medical school.

Table 1
American vs. Foreign Graduates in NC Practice

Medical School	No. of Graduates		N.C. Practice	
American		17		10
North Carolina	6		6	
Other State	11		4	
Foreign		6		5
Total		23		15 (65%)

Table 2
Practice Site: North Carolina, Adjacent State, or Distant State

Medical School	No. of Graduates	Practice Site		
		North Carolina	Adjacent	Distant
Adjacent State	5	3	2	0
Distant State	6	1	2	3

From the Department of Medicine, New Hanover Memorial Hospital, Wilmington 28401.

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Reduces angina attack frequency*
42% to 46% decrease reported in multicenter study.[1]

Increases exercise tolerance*
In Bruce exercise test,[2] control patients averaged 8.0 minutes to onset of pain; Cardizem patients averaged 9.8 minutes ($P<.005$).

CARDIZEM®
(diltiazem HCl)

THE BALANCED CALCIUM CHANNEL BLOCKER

Please see full prescribing information on following page.

2/84

*Cardizem is indicated in the treatment of angina pectoris due to coronary artery spasm and in the management of chronic stable angina (classic effort-associated angina) in patients who cannot tolerate therapy with beta-blockers and/or nitrates or who remain symptomatic despite adequate doses of these agents.

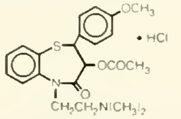
References:
1. Strauss WE, McIntyre KM, Parisi AF, et al: Safety and efficacy of diltiazem hydrochloride for the treatment of stable angina pectoris: Report of a cooperative clinical trial. Am J Cardiol 49:560-566, 1982.
2. Pool PE, Seagren SC, Bonanno JA, et al: The treatment of exercise-inducible chronic stable angina with diltiazem: Effect on treadmill exercise. Chest 78 (July suppl):234-238, 1980.

PROFESSIONAL USE INFORMATION

cardizem®
(diltiazem HCl)
30 mg and 60 mg tablets

DESCRIPTION

CARDIZEM® (diltiazem hydrochloride) is a calcium ion influx inhibitor (slow channel blocker or calcium antagonist). Chemically, diltiazem hydrochloride is 1,5-Benzothiazepin-4(5H)one,3-(acetyloxy)-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-, monohydrochloride,(+)-cis- The chemical structure is



Diltiazem hydrochloride is a white to off-white crystalline powder with a bitter taste It is soluble in water, methanol, and chloroform It has a molecular weight of 450.98. Each tablet of CARDIZEM contains either 30 mg or 60 mg diltiazem hydrochloride for oral administration

CLINICAL PHARMACOLOGY

The therapeutic benefits achieved with CARDIZEM are believed to be related to its ability to inhibit the influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle

Mechanisms of Action. Although precise mechanisms of its antianginal actions are still being delineated, CARDIZEM is believed to act in the following ways

1. Angina Due to Coronary Artery Spasm CARDIZEM has been shown to be a potent dilator of coronary arteries both epicardial and subendocardial. Spontaneous and ergonovine-induced coronary artery spasm are inhibited by CARDIZEM
2. Exertional Angina CARDIZEM has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand. This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal exercise work loads

In animal models, diltiazem interferes with the slow inward (depolarizing) current in excitable tissue It causes excitation-contraction uncoupling in various myocardial tissues without changes in the configuration of the action potential Diltiazem produces relaxation of coronary vascular smooth muscle and dilation of both large and small coronary arteries at drug levels which cause little or no negative inotropic effect The resultant increases in coronary blood flow (epicardial and subendocardial) occur in ischemic and nonischemic models and are accompanied by dose-dependent decreases in systemic blood pressure and decreases in peripheral resistance.

Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, diltiazem decreases sinoatrial and atrioventricular conduction in isolated tissues and has a negative inotropic effect in isolated preparations In the intact animal, prolongation of the AH interval can be seen at higher doses.

In man, diltiazem prevents spontaneous and ergonovine-provoked coronary artery spasm. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load. Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative inotropic effect, cardiac output, ejection fraction, and left ventricular end diastolic pressure have not been affected. There are as yet few data on the interaction of diltiazem and beta-blockers Resting heart rate is usually unchanged or slightly reduced by diltiazem.

Intravenous diltiazem in doses of 20 mg prolongs AH conduction time and AV node functional and effective refractory periods approximately 20%. In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block Diltiazem-associated prolongation of the AH interval is not more pronounced in patients with first-degree heart block In patients with sick sinus syndrome, diltiazem significantly prolongs sinus cycle length (up to 50% in some cases).

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PR interval, but has not usually produced abnormal prolongation. There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients.

Pharmacokinetics and Metabolism. Diltiazem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive first-pass effect, giving an absolute bioavailability (compared to intravenous dosing) of about 40% CARDIZEM undergoes extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the urine In vitro binding studies show CARDIZEM is 70% to 80% bound to plasma proteins. Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, hydrochlorothiazide, phenylbutazone, propranolol, salicylic acid, or warfarin Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours Desacetyl diltiazem is also present in the plasma at levels of 10% to 20% of the parent drug and is 25% to 50% as potent a coronary vasodilator as diltiazem Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 ng/ml. There is a departure from dose-linearity when single doses above 60 mg are given, a 120-mg dose gave blood levels three times that of the 60-mg dose There is no information about the effect of renal or hepatic impairment on excretion or metabolism of diltiazem

INDICATIONS AND USAGE

1. **Angina Pectoris Due to Coronary Artery Spasm.** CARDIZEM is indicated in the treatment of angina pectoris due to coronary artery spasm CARDIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occurring during attacks)
2. **Chronic Stable Angina (Classic Effort-Associated Angina).** CARDIZEM is indicated in the management of chronic stable angina CARDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise tolerance.

There are no controlled studies of the effectiveness of the concomitant use of diltiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

1. **Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0 48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem
2. **Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited Caution should be exercised when using the drug in such patients.
3. **Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension
4. **Acute Hepatic Injury.** In rare instances, patients receiving CARDIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes (See PRECAUTIONS and ADVERSE REACTIONS)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals The drug should be used with caution in patients with impaired renal or hepatic function In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM (See WARNINGS).

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity There was also no mutagenic response in in vitro bacterial tests No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality These doses, in some studies, have been reported to cause skeletal abnormalities In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus

Nursing Mothers. It is not known whether this drug is excreted in human milk Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this situation

Pediatric Use. Safety and effectiveness in children have not been established

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences, as well as their frequency of presentation, are edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%), AV block (1.1%). In addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence

Cardiovascular	Flushing, arrhythmia, hypotension, bradycardia, palpitations, congestive heart failure, syncope
Nervous System	Paresthesia, nervousness, somnolence, tremor, insomnia, hallucinations, and amnesia
Gastrointestinal	Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH
Dermatologic	Pruritus, petechiae, urticaria, photosensitivity
Other	Polyuria, nocturia.

The following additional experiences have been noted:

A patient with Prinzmetal's angina experiencing episodes of vasospastic angina developed periods of transient asymptomatic asystole approximately five hours after receiving a single 60-mg dose of CARDIZEM

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM erythema multiforme, leukopenia, and extreme elevations of alkaline phosphatase, SGOT, SGPT, LDH, and CPK However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established

OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diltiazem has been limited Single oral doses of 300 mg of CARDIZEM have been well tolerated by healthy volunteers In the event of overdosage or exaggerated response, appropriate supportive measures should be employed in addition to gastric lavage The following measures may be considered

Bradycardia	Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.
High-Degree AV Block	Treat as for bradycardia above Fixed high-degree AV block should be treated with cardiac pacing
Cardiac Failure	Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics
Hypotension	Vasopressors (eg, dopamine or levarterenol bitartrate).

Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating physician

The oral/LD_{50}'s in mice and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively The intravenous LD_{50}'s in these species were 60 and 38 mg/kg, respectively The oral LD_{50} in dogs is considered to be in excess of 50 mg/kg, while lethality was seen in monkeys at 360 mg/kg The toxic dose in man is not known, but blood levels in excess of 800 ng/ml have not been associated with toxicity

DOSAGE AND ADMINISTRATION

Exertional Angina Pectoris Due to Atherosclerotic Coronary Artery Disease or Angina Pectoris at Rest Due to Coronary Artery Spasm. Dosage must be adjusted to each patient's needs. Starting with 30 mg four times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four times daily) at one- to two-day intervals until optimum response is obtained Although individual patients may respond to any dosage level, the average optimum dosage range appears to be 180 to 240 mg/day There are no available data concerning dosage requirements in patients with impaired renal or hepatic function. If the drug must be used in such patients, titration should be carried out with particular caution.

Concomitant Use With Other Antianginal Agents:

1. **Sublingual NTG** may be taken as required to abort acute anginal attacks during CARDIZEM therapy.
2. **Prophylactic Nitrate Therapy** — CARDIZEM may be safely coadministered with short- and long-acting nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination
3. **Beta-blockers.** (See WARNINGS and PRECAUTIONS.)

HOW SUPPLIED

Cardizem 30-mg tablets are supplied in bottles of 100 (NDC 0088-1771-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1771-49). Each green tablet is engraved with MARION on one side and 1771 engraved on the other CARDIZEM 60-mg scored tablets are supplied in bottles of 100 (NDC 0088-1772-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1772-49). Each yellow tablet is engraved with MARION on one side and 1772 on the other

Issued 4/1/84

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TOXIC ENCOUNTERS

Cyrano De Bergerac Would Have Loved 1,1,1-trichloroethane

Ronald B. Mack, M.D.

• *If your secretary is making more typos and enjoying them more as well, check your correction fluid supply.*

PROBABLY one of the greater perquisites of being a professional is that you can utilize the services of a secretary. I frankly would be lost without mine (are you listening, Debbie Weatherman?). Lately some of you may have noticed that your secretary has been making more typing mistakes and seems to be enjoying the errors and, furthermore, the more typos the more happiness. Possibly she or he is "turning on" to the typewriter correction fluid which has become another in the long list of substances that can cause a "high" (in some instances you get so high you touch the sky and never come down again). This form of self destruction is becoming popular among sophisticated teenagers as well.

Typewriter correction fluids, e.g., Wite-Out, Liquid Paper, etc., are chlorinated solvents that are inexpensive and very available at your local supermarket, drug store, office supply, discount store or variety store. The major ingredients of these fluids, for the purposes of our discussion, are 1,1,1-trichloroethane, AKA methyl chloroform and henceforth referred to here as *TCA*, and trichloroethylene — TCE. You might recall that in the past both of these chemicals have been utilized as general anesthetic agents but have subsequently been replaced by safer chemicals.

The inhalation of volatile substances to produce a "psychedelic" experience has certainly been much in evidence in this post World War II Age of Aquarius. That euphoria can be by the induced inhalation of chloroform, carbon tetrachloride perchloroethylene, toluene, gasoline, or benzene is yesterday's news. It seems that today's thrill seekers are searching for newer and better ways to alter their consciousness. Does it not seem to you that man has attempted to undergo changes in his/her mental status throughout history by using chemicals? Usually the drug was taken orally, but no body orifice has remained chaste as even cursory reading of the history of medicine can attest.

Possibly the ear has remained the most virginal in terms of accepting chemical substances that can produce general as opposed to local deviations of homeostasis. My absolute favorite ear story involves the "murder most foul" of Hamlet's father by the young Danish prince's uncle-stepfather, Claudius. If you recall the story, Hamlet's father (in the form of a ghost) explains to our protoganist that he was killed by the introduction of the "juice of the cursed hebenon" into his ear which subsequently caused his premature demise. How could Shakespeare have made up such a story? Was this the science fiction of that era? According to a recent article,[1] Shakespeare may well have known about the work of Bartolommeo Eustachio who published his classic studies almost a half century before Hamlet was first performed on the stage. Apparently chronic purulent otorrhea was relatively common in Elizabethan times and furthermore it is strongly alleged that medical personnel of those times knew that middle ear fluids could drain into the pharynx and thus a substance, toxic or otherwise, could be instilled into the external auditory canal, transverse a perforation of the tympanic membrane, enter the pharynx by way of the eustachian tube and then be swallowed and absorbed via the GI tract. It is further alleged that the "cursed hebenon" was actually henbane, obtained from the plant of the hyoscyamus species. For those of you who have spouses or co-renters who bear evil thoughts toward you I suggest you invest in a pair of ear plugs — is nothing sacred anymore?

But I digress — probably because I have made so many mistakes typing this that I have "used" one half bottle of typewriter correction fluid. TCA can be readily absorbed via the skin, GI tract, and lungs; it is very very volatile and is absorbed most significantly through the respiratory system. If you accidentally or purposely swallow this solvent you can experience nausea, vomiting, abdominal pain, and diarrhea within 30-60 minutes along with confusion, agitation, amnesia, lethargy and dizziness not to mention ventricular arrhythmia and death. An important clinical clue is the odor of hydrocarbons detected in the effluvium from the gastrointestinal tract. Dermal contact with these chlorinated solvents can potentially cause systemic adversities but that is unlikely. First and second degree burns can occur, however, as can various irritating dermatitides and staining of the skin.

For most health care professionals who encounter a patient undergoing a toxic episode resulting from TCA or TCE or the like, it will most likely be due to the patient's *inhalation* of one of these chemicals. It is entirely possible that your first encounter with such a patient will be to

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pronounce him or her dead. These substances are "sniffed" by the user to obtain a state of euphoria but larger acute inhalations proceed to dizziness, weakness and then progress to unconsciousness, seizures, as well as respiratory depression and cardiovascular collapse. In addition to these major insults, the toxins very adversely affect the myocardium by causing a sudden release of catecholamines which may then predispose the heart to fatal dysrhythmias. It should be noted here that people who inhale euphoriants such as typewriter correction fluids do so by several methods: there are the **"huffers"** — who spray or pour the liquid onto a cloth which is then placed near the mouth or rolled into a tube and inhaled; the **"baggers"** — this method is used by the cognoscenti who place the substance to be inhaled into a plastic bag or other container while placing the open end of the bag over the head or face and breathing in the vapor. This method quite obviously lends itself to producing suffocation. Finally there is the more mundane user, known as the **"sniffer,"** who merely inhales the vapor by placing his/her nose over the opening of the container. The inhalation of solvents, such as trichloroethane, can lead to the "sudden sniffing death syndrome."[2] In this syndrome the act of inhaling the solvents plus exercise or stress causes a release of catecholamines which apparently potentiates the adverse effects of the inhalant on the myocardium resulting in severe cardiac arrhythmia and death. (I recently saw an intern die from the "sudden sniffing death syndrome" after asking one of his teenage patients in the clinic to remove his "sneakers.") A typical scenario of such an ignoble demise could be something like this: At midmorning you admonish your secretary for fouling up your appointments beyond all recognition — (known as FUBAR) — as well as producing more typos per square inch than usual. Your tirade causes your secretary to seek solace; she takes several "sniffs" of her typewriter correction fluid hoping to induce an euphoric state and assuage her feelings of incompetence. She begins to re-type the data requested and this time the old typos are corrected but untold new ones appear, like mushrooms after a rain storm. You explode in fury and question your secretary's parentage, IQ, hat size, etc. The humiliated employee appears quite anxious at this point and runs to the rest room only to collapse and die in the 3rd stall.

It is not always easy to diagnose a typewriter correction abuser. Of course it helps to know if the patient has a history of "sniffing" similar substances in the past. It most certainly helps you to make the diagnosis if the patient's breath smells like hydrocarbons and if there are opaque stains around the nose, hands, and clothing in an obtunded patient.

Assuming you are confronted by a patient who gets involved with one of these inhalant solvents and is still alive, what can you do to help? The treatment is essentially supportative; there are no "magic bullets" for this problem. The patient should be placed in a quiet nonthreatening environment in an effort to reduce the risk of further catecholamine release. Give oxygen if the patient is hypoxic and whatever you do, *do not give sympathomimetic drugs* such as isoproterenol or epinephrine. If you administer such a medication they may say of you "the patient was at death's door and the doctor pulled him through" — the wrong direction unfortunately. Beta blocking agents could be used to offset ventricular arrhythmias should they arise. Diazepam, given intravenously, is advised for seizures.

Why would anyone want to shove stuff up their nose on purpose? I don't know about you, but I don't mess with my nose — it's off limits — taboo — even for fingers. Apparently, inhaling 1,1,1-trichloroethane causes an euphoric state similar to alcohol-induced inebriation. Hallucinations may occur. The effect is often quite transitory so further inhalations are employed. I suppose having a big nose helps. Cyrano De Bergerac (the hero of the play by the same name, written by Edmond Rostraud[3]) probably had the biggest beak in modern literature. Cyrano was a "gallant soldier, brilliant wit, remarkable swordsman and a tragic poet but had the face of a clown." Early in the play his nasal appendage is described as follows, "My lords, there is no such nose as that nose — you cannot look upon it without crying, Oh, no, Impossible! Exaggerated!" Then you smile and say, "Of course — I might have known; presently he will take it off." Well, the nose did not come off, but Cyrano could have taken one snort of trichloroethane and had a world class "high."

The only real antidote to this problem is to buy your secretary a word processor.

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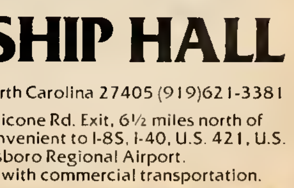

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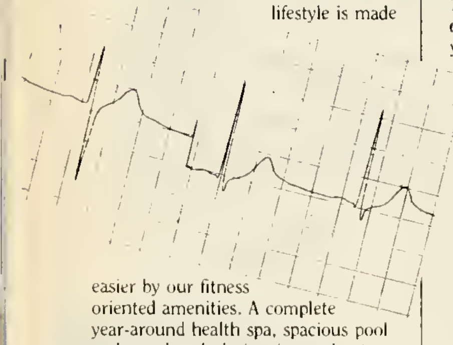

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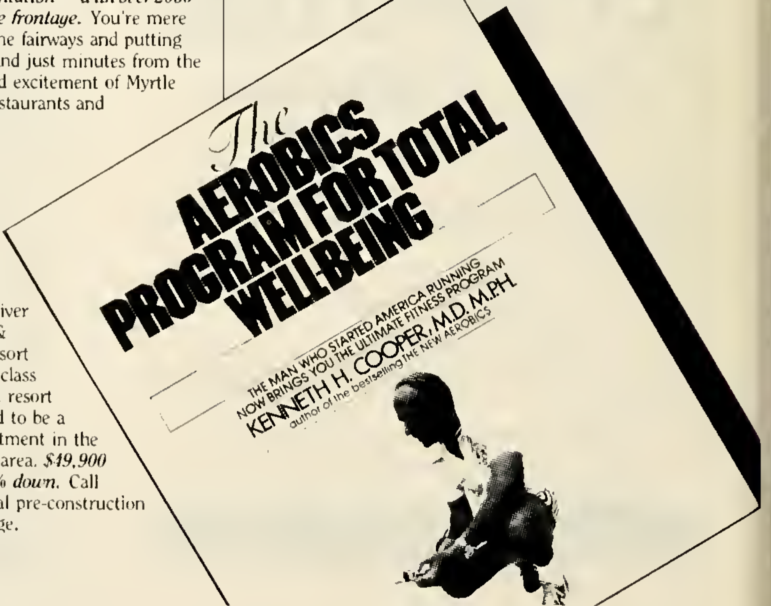
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SOCIOECONOMIC ISSUES

Talking With Your Retirement Plan Advisor: Overcoming the Language Barrier

Walter R. Rogers, Jr., J.D. and Jennifer M. Dibble, J.D.

I. Introduction

Your retirement plan advisor is, or should be, an expert. Like all experts, he uses a specialized vocabulary for his technical descriptions. Just as physicians try to phrase advice in language patients can understand, good retirement plan advisors try to explain retirement planning in language clients can understand. However, the good intentions of even the best advisors often fall victim to time pressures. As a result, a client may adopt a retirement plan well suited to his needs but may also be left uneasy about how the plan works or why he chose it over other alternatives. We hope to help you overcome the language barrier posed by retirement plan advisors' specialized vocabulary by providing a glossary of some common qualified retirement plan terms you are likely to encounter.

II. Types of Qualified Retirement Plans

A. "Qualified" Retirement Plans.

"Qualified" retirement plans meet certain tax law requirements and therefore qualify for special tax treatment. The requirements for qualification are numerous, but they are grounded in certain basic policies. The terms or operation of a qualified retirement plan cannot unduly favor officers, shareholders or highly-compensated employees. This policy underlies the requirements that officers, shareholders or highly-compensated employees (sometimes called the "prohibited group") cannot enter the plan sooner, receive a higher percentage of pay as benefits or have a higher percentage of pay contributed to the plan, or become entitled to their benefits faster than other employees. Another major policy is that employees must know their rights under plans. This policy underlies the requirements that plans must be written, must be communicated to employees, and must contain definitely determinable benefits.

In return for meeting the tax law requirements, a qualified retirement plan receives several tax advantages. First, the employer who contributes funds to a qualified plan can deduct those contributions, within limits, from the employer's income for the year of the contribution. Second, as the retirement plan funds earn income, the increase in the funds is not taxed but accumulates tax-free until distribution. Third, the employee is not taxed on the contributions made on his behalf by the employer until the employee receives funds from the plan. Fourth, certain plan distributions may qualify for capital gains or income averaging tax treatment.

The following illustration shows why many physicians find qualified retirement plans attractive. The illustration compares Practice A which does not have a plan with Practice B which has a simple qualified defined contribution plan. Practice B contributes an amount equal to 10% of each employee's compensation to its plan and pays the rest of its income out in salary or bonus. After subtracting tax at an assumed effective rate of 35% from each physician's income, the physician's net increase in wealth is larger in Practice B than in Practice A. The physician in Practice B also has a smaller current income tax liability and provides a retirement benefit for his staff. Of course, eventually the physician in Practice B will pay income tax on the distribution he receives from his plan, but in the interim he enjoys the benefits of tax deferral.

	Practice A	Practice B
Income of Practice	$200,000	$200,000
Salaries and Bonuses		
Physician	185,000	166,818*
Nurse	15,000	15,000
Contribution to Plan		
For Physician	-0-	16,682
For Nurse	-0-	1,500
Physician's Benefit		
Salary and bonus	185,000	166,818
Less income tax	(64,750)	(58,386)
Plan contribution	-0-	16,682
Benefit	$120,250	$125,114

* The physician computes his compensation by subtracting fixed costs (nurse's salary — $15,000 and plan contribution for nurse — $1,500) from practice income ($200,000). Since the plan is a 10% plan, the result ($183,500) is 110% of the physician's compensation. Therefore the physician takes home (usually as a combination of monthly salary and year-end bonus) $166,818 (subject to tax) and contributes $16,682 to the plan on his own behalf.

Of course, in order to benefit from a qualified plan, the physician in Practice B must be able to give up the immediate use of amounts contributed to the plan. This is why retirement advisors look at a physician's current cash requirements to determine how much deferral he can afford.

B. "Defined Contribution" Plans.

A "defined contribution" plan is a type of qualified plan which states the amount that the employer will contribute to the plan on behalf of employees each year. The employer's

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contribution is allocated among the employees' "accounts" according to a formula in the plan. An employee's "account balance" consists of his share of the employer's contributions to the plan (and the investment return on those contributions), any contributions the employee makes to the plan, and a pro rata share of amounts forfeited by other employees who leave employment before being entitled to some or all of their account balances. An employee's retirement benefit from a defined contribution plan is his account balance at retirement.

Tax law imposes limits on the amount which may be added to an employee's account annually under a defined contribution plan. An employee's account can receive no more than the lesser of $30,000 or 25% of the employee's compensation each year from employer contributions, certain employee contributions, and forfeitures. The conventional wisdom is that a defined contribution plan is best for younger employees who stay with the employer for a substantial period of time. This is because annual contributions made over a long period of time (and the investment return on those contributions) can result in large account balances. A defined contribution plan is also relatively simple to administer.

1. *"Money purchase" plans.*

A "money purchase" plan is a qualified defined contribution plan that states in definite terms the amount that an employer will contribute to the plan each year.

2. *"Profit sharing" plans.*

A "profit sharing" plan is a defined contribution plan to which an employer contributes a percentage of profits each year. Some profit sharing plans state the percentage of earnings and profits that the employer will contribute each year. Other profit sharing plans permit a year-to-year determination of the amount of profits an employer will contribute. Obviously, an employer who is uncertain of its ability to contribute to a qualified retirement plan each year will find the flexibility of a profit sharing plan appealing. The tax law generally restricts the employer's deduction for amounts contributed to a profit sharing plan to 15% of employees' compensation, which is lower than the limit for employer deductions for contributions to other types of plans.

3. *"Cash or deferred" or "401(k)" plans.*

A fairly recent addition to retirement planning vocabulary is the "cash or deferred" or "401(k)" plan. A 401(k) plan is actually a type of profit sharing plan. Cash or deferred refers to the choice given an employee to defer income by having the employer contribute a percentage of the employee's pay to the profit sharing plan or to receive it as current cash compensation. Section 401(k) is the section of the Internal Revenue Code that permits such a plan. A 401(k) plan can be a "salary reduction" plan in which an employee reduces his current stated salary by electing to defer some of it. Another type of 401(k) plan is a "bonus plan" which gives an employee the choice to receive or defer amounts paid in addition to regular salary.

The attraction of a 401(k) plan is the flexibility it gives employees. Frequently employees have different cash needs. Some can defer the maximum permissible contribution until retirement while others need current cash. However, a 401(k) plan is administratively complex. The higher-paid one-third employees cannot defer amounts in excess of a certain percentage of amounts deferred by the lower-paid two-thirds employees. In practice this means that unless many of the lower-paid employees elect to defer, the higher-paid employees cannot defer as much as they may wish.

C. "Defined Benefit" Plans.

A "defined benefit" plan is a type of qualified plan that states the amount a participant will receive from the plan at retirement. The employer uses the services of an actuary to calculate what contributions the employer must make to achieve the level of benefits promised each employee. The actuary makes assumptions about employment habits, mortality and return on investments. If the employer's experience differs from the actuary's assumptions, the employer will adjust the contributions to the plan accordingly. Thus, in contrast to a defined contribution plan, a defined benefit plan puts the risk of investment return and other variables on the employer.

The conventional wisdom is that a defined benefit plan favors older employees with a relatively short time to retirement. Such employees would not be able to accumulate much retirement capital in a defined contribution plan because of the limits on annual additions to such plans. However, an employee retiring at age 62 or older may currently receive at retirement from a defined benefit plan as much as the lesser of $90,000 per year or 100% of average compensation for the highest-paid three years of employment. To meet this benefit over a short period of employment the employer will have to contribute large amounts to the defined benefit plan each year, which is useful to an employer who wants a large tax deduction. A drawback to the defined benefit plan is its complexity, which makes its administration more expensive than that of a defined contribution plan.

Defined benefit plans differ according to the formulae used for calculating benefits. Some plans state that benefits will be a percentage of final average compensation while some calculate benefits as a percentage of an employee's highest annual compensation amounts. Others multiply a percentage of compensation times an employee's number of years of employment.

D. "Keogh" or "HR-10" Plans.

Before the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), tax law imposed special limits on qualified retirement plans for self-employed individuals such as sole practitioners and partners in a medical practice. Plans which covered self-employed individuals were known as "Keogh" or "HR-10" plans and were in many ways less attractive than corporate qualified plans. By 1982, Congress had realized that some persons who might otherwise operate as sole proprietors or in partnerships were incorporating under "professional association" laws just to avoid Keogh plan limitations. In TEFRA Congress eliminated most distinctions between Keogh plans and qualified retirement plans for corporations. Congress achieved this "parity" between Keogh plans and corporate plans by eliminating some of the Keogh plan restrictions and by extending other Keogh-like restrictions to all "top heavy" plans, whether corporate or noncorporate. (Our next article discusses "top heavy" plans.) Some distinctions between corporate and noncorporate qualified retirement plans remain, however, such as restrictions on borrowing from qualified retirement plans.

If you have not incorporated your practice and you have not had your qualified retirement plan reviewed since 1982, you should check with your retirement plan advisor to see if your plan is unduly restrictive. If you are debating whether or not to incorporate your practice, remember that although TEFRA eliminated most distinctions between corporate and noncorporate qualified retirement plans, corporations and corporate employees still receive special tax treatment with respect to certain other fringe benefits.

E. "IRAs."

Given the media blitz by brokerage houses and banks, everyone should know everything there is to know about individual retirement accounts or "IRAs." One fact that people sometimes forget is that anyone who receives earned income can establish an IRA even if he is also covered by a qualified retirement plan. Thus, even if you have already established a qualified retirement plan in your practice, you can contribute a maximum of the lesser of $2,000 ($2,250 if your spouse does not have any earned income) or 100% of your earned income per year to an IRA. You can deduct the amount contributed to the IRA from your income in figuring your taxes, and the IRA's earnings accumulate tax free. Of course, there are restrictions on IRAs: one cannot withdraw the funds without penalty before age 59½; one must begin to withdraw funds by age 70½; one cannot invest IRA funds in collectibles; and one can only contribute cash to the IRA. However, unlike qualified retirement plans, the tax benefits of IRAs are available to you without the expense of having to cover your employees.

III. Plan Provisions

A. "Participation."

1. Coverage.

Once you have decided that the tax benefits of a qualified retirement plan are attractive, you need to determine its cost. Key to determining cost is determining how many of your employees your plan must cover, because not only must your plan cover you, but it must cover some or all of your employees. In order for a retirement plan to be qualified, it must meet one of three "participation" tests. Most physicians' plans meet the "70% test." The "70% test" requires that the plan cover 70% of the employer's employees, except for employees who have not met certain age and service requirements. Employees whom the plan covers are called "participants."

2. Age and Service Requirements.

An employer can exclude employees from its qualified retirement plan because of their age or because they have not worked for the employer long enough, within limits. The maximum the employer can require, with one exception, is that its plan not cover an employee until the later of his twenty-fifth birthday or the anniversary of one year's employment. The exception is that an employer can require an employee to work for the employer for as long as three years before covering him if the employee is then entitled to all of his share of contributions made to the plan should he leave employment. Under a defined benefit plan, the employer can also exclude employees who begin working at an age within five years of the normal retirement age stated in the plan.

B. "Vesting."

What happens to a participant's share of contributions made to the plan if he leaves employment before retirement? In some cases, the participant may be entitled to nothing and "forfeit" his share of plan assets. The forfeited amount is divided among remaining participants and usually reduces the employer's contribution to the plan. Generally, however, a plan must provide that participants who leave after several years of employment but before retirement be "vested" in some or all of their share of plan assets. "Vested" means that those assets cannot be forfeited and allocated to anyone else but must go to the participant. The vested assets may be kept in the plan until the departing participant reaches retirement age or may be paid out to the participant before retirement age.

1. "Cliff Vesting."

There are many permissible vesting schedules, but physicians' plans must usually contain liberal vesting schedules. "Cliff vesting" provides that a participant is entitled to nothing until he works a certain period of time. After that time the participant is 100% vested. Since TEFRA, most physicians' plans using cliff vesting can require only three years of employment without any vesting. (Remember, if the plan requires that employees work three years before participating in the plan, they must be 100% vested in their share of contributions from the first year of participation.)

2. "Graded Vesting."

Another type of vesting is "graded vesting." Under graded vesting an employee is entitled to a larger percentage of his share of contributions each year until he is 100% vested. Before TEFRA, the IRS found "4-40 vesting" acceptable in many physicians' plans. An employee would not be vested at all until the fourth year of employment. In the fourth year, the employee would be 40% vested. Another 5% vesting would be added each of the next two years and 10% vesting each of the following five years. In the eleventh year of employment the employee would be 100% vested. Now if you choose to use graded vesting, you may be required to use "six year graded vesting." After two years of employment, each employee will be vested in 20% of his share of contributions and 20% will be added each following year. The employee will be 100% vested after six years of employment.

3. Employee Contributions.

Finally, an employee is always completely vested in any

Table 1.
Comparison of Non-integrated and Integrated Plans

a. Non-integrated Plan

Participant	*Compensation*	*10% of Compensation*	*Plan Contribution*
Physician	$150,000	$15,000	$15,000
Nurse	15,000	1,500	1,500
		Total Contribution to Plan:	$16,500

b. Integrated Plan

Participant	*Compensation*	*5% of $15,000*	*10.7% of Excess*	*Plan Contribution*
Physician	$150,000	$750.00	$14,445	$15,195
Nurse	15,000	750.00	-0-	750
			Total Contribution to Plan:	$15,945

contribution the employee makes to the plan. This includes amounts he elects to defer under a 401(k) plan. This makes sense because, after all, the employee could have received the amounts deferred in a 401(k) plan immediately as cash.

C. "Discrimination" and "Integration."

1. "Discrimination."

Qualified retirement plans cannot "discriminate." This means they cannot favor officers, shareholders or highly-compensated employees over the employer's other employees. The prohibition against discrimination does not mean that all contributions an employer makes on behalf of employees under a defined contribution plan or all benefits a defined benefit plan pays to retired employees must be equal. Rather, the law provides that as long as those allocations or benefits reflect a uniform percentage of each employee's compensation, the plan is non-discriminatory. Thus, the allocation formula in a qualified defined contribution plan can allocate $25,000 to a physician's account, representing 25% of his $100,000 annual compensation, and $2,500 to a staff member's account, representing 25% of the staff member's $10,000 annual compensation. Similarly, a qualified defined benefit plan may pay an annual benefit of $90,000 to a retired physician and $10,000 to a retired staff member representing 100% of the physician's and staff member's final compensation.

2. "Integration."

When retirement plan advisors speak of "integration" they mean the process of combining the Social Security system with the employer's qualified retirement plan. An employer with a qualified defined contribution plan can count contributions made to the Social Security system on behalf of an employee as if the employer made those contributions to the employer's plan. An employer with a qualified defined benefit plan can count the benefits an employee receives from the Social Security system as if the employer's plan paid the benefits.

Integration can be a cost-saving feature in a qualified retirement plan. Naturally there are many rules regarding how an employer can integrate a plan. In a defined contribution plan, for example, an employer can contribute a certain percentage of compensation under the "integration level" and a higher percentage (currently a maximum of 5.7 percentage points higher) of compensation over the "integration level." The "integration level" is any compensation cut-off point the employer chooses, although if the employer uses a higher integration level than the Social Security wage base (currently $37,800) the employer must adjust the difference in contribution percentages downward. Retirement plan advisors generally recommend an integration level for physician's plans at or slightly above the highest staff salary for maximum cost efficiency.

Integrating a defined benefit plan is more difficult and depends on the benefit formula in the plan. However, the theory is similar since it allows employers to integrate the benefits a retired employee will receive from the Social Security system with the benefits he will receive from the plan. For example, one type of integrated defined benefit plan allows an employer to "offset" the benefits its qualified retirement plan provides with the benefits the Social Security system provides. As a result, the employer can reduce its contribution to the defined benefit plan.

Table 1 compares a non-integrated defined contribution plan with an integrated defined contribution plan. The integrated plan has an integration level of $15,000 and 5.7 percentage points difference between the two contribution percentages. You can see that with an integrated defined contribution plan the physician can make higher contributions to his own account while reducing the overall cost of the plan.

IV. Conclusion

We have just taken a glance at the tip of an iceberg. We hope that a basic understanding of some of the more common qualified retirement plan terms will help you communicate more efficiently with your retirement plan advisor. Our next article will cover in more detail recent tax law changes in this area, including the changes requiring plan amendments many of you are or will be adopting before the end of this year.

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See important information on next page.

For relief of musculoskeletal sprains, strains, aches and pains, when accompanied by anxiety...

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Equagesic®
(meprobamate with aspirin) ⓒ Wyeth

(BRIEF SUMMARY)

DESCRIPTION
Each tablet contains 200 mg meprobamate and 325 mg aspirin

INDICATIONS
Adjunct in short-term treatment of pain accompanied by tension and or anxiety in patients with musculoskeletal disease Clinical trials demonstrated that in these situations relief of pain is somewhat greater than with aspirin alone Effectiveness in long-term use i e over 4 months, has not been assessed by systematic clinical studies Physicians should periodically reassess usefulness of drug for individual patients

CONTRAINDICATIONS
ASPIRIN Allergic or idiosyncratic reactions to aspirin or related compounds

MEPROBAMATE Acute intermittent porphyria allergic or idiosyncratic reactions to meprobamate or related compounds e g carisoprodol mebutamate or carbromal

WARNINGS
ASPIRIN Use salicylates with extreme caution in patients with peptic ulcer asthma coagulation abnormalities hypoprothrombinemia, vitamin K deficiency or those on anticoagulants In rare instances, aspirin in persons allergic to salicylates may result in life-threatening allergic episodes

MEPROBAMATE DRUG DEPENDENCE
Physical and psychological dependence and abuse have occurred Chronic intoxication from prolonged ingestion of usually greater than recommended doses is manifested by ataxia slurred speech and vertigo Therefore, carefully supervise dose and amounts prescribed and avoid prolonged use especially in alcoholics and others with known propensity for taking excessive quantities of drugs Sudden withdrawal after prolonged and excessive use may precipitate recurrence of preexisting symptoms e g anxiety anorexia or insomnia or withdrawal reactions, e g vomiting ataxia tremors, muscle twitching confusional states hallucinosis and rarely convulsive seizures Such seizures are more likely in persons with CNS damage or preexistent or latent convulsive disorders Onset of withdrawal symptoms occurs usually within 12 to 48 hours after discontinuation, symptoms usually cease within next 12- to 48-hour period When excessive dosage has continued for weeks or months, reduce dosage gradually over 1 to 2 weeks rather than stop abruptly Alternatively a short acting barbiturate may be substituted then gradually withdrawn

POTENTIALLY HAZARDOUS TASKS Warn patients meprobamate may impair mental or physical abilities required for potentially hazardous tasks e g driving or operating machinery

ADDITIVE EFFECTS Since CNS-suppressant effects of meprobamate and alcohol or meprobamate and other psychotropic drugs may be additive exercise caution with patients taking more than one of these agents simultaneously

USAGE IN PREGNANCY AND LACTATION
An increased risk of congenital malformations associated with minor tranquilizers (meprobamate, chlordiazepoxide, and diazepam) during first trimester of pregnancy, has been suggested in several studies Because use of these drugs is rarely a matter of urgency, their use during this period should almost always be avoided The possibility that a woman of childbearing potential may be pregnant at time of institution of therapy should be considered. Advise patients if they become pregnant during therapy or intend to become pregnant to communicate with their physicians about desirability of discontinuing the drug

Meprobamate passes the placental barrier It is present both in umbilical-cord blood at or near maternal plasma levels and in breast milk of lactating mothers at concentrations two to four times that of maternal plasma When use of meprobamate is contemplated in breastfeeding patients, consider the drug a higher concentrations in breast milk as compared to maternal plasma levels

USAGE IN CHILDREN Keep preparations with aspirin out of reach of children Equagesic® (meprobamate with aspirin) is not recommended for patients 12 years of age and under

PRECAUTIONS
ASPIRIN Salicylates antagonize uricosuric activity of probenecid and sulfinpyrazone Salicylates are reported to enhance hypoglycemic effect of sulfonylurea antidiabetics

MEPROBAMATE Use lowest effective dose particularly in elderly and/or debilitated, to preclude over-sedation Meprobamate is metabolized in the liver and excreted by the kidney to avoid excess accumulation exercise caution in its use in patients with compromised liver or kidney function Meprobamate occasionally may precipitate seizures in epileptic patients It should be prescribed cautiously and in small quantities to patients with suicidal tendencies

ADVERSE REACTIONS
ASPIRIN May cause epigastric discomfort nausea and vomiting Hypersensitivity reactions including urticaria, angioneurotic edema, purpura asthma, and anaphylaxis may rarely occur Patients receiving large doses of salicylates may develop tinnitus

MEPROBAMATE CNS Drowsiness, ataxia, dizziness, slurred speech, headache vertigo, weakness, paresthesias, impairment of visual accommodation, euphoria, overstimulation paradoxical excitement fast EEG activity

GI Nausea vomiting, diarrhea

CARDIOVASCULAR Palpitation, tachycardia various forms of arrhythmia, transient ECG changes, syncope, hypotensive crisis

ALLERGIC OR IDIOSYNCRATIC Milder reactions are characterized by itchy urticarial or erythematous maculopapular rash generalized or confined to the groin Other reactions include leukopenia, acute nonthrombocytopenic purpura, petechiae, ecchymoses eosinophilia peripheral edema adenopathy fever fixed drug eruption with cross-reaction to carisoprodol and cross sensitivity between meprobamate/mebutamate and meprobamate/carbromal Rare more severe hypersensitivity reactions include hyperpyrexia, chills, angioneurotic edema, bronchospasm oliguria, and anuria Also, anaphylaxis, exfoliative dermatitis, stomatitis and proctitis Stevens-Johnson syndrome and bullous dermatitis have occurred

HEMATOLOGIC (SEE ALSO "ALLERGIC OR IDIOSYNCRATIC") Agranulocytosis, aplastic anemia have been reported, although no causal relationship has been established, and thrombocytopenic purpura

OTHER Exacerbation of porphyric symptoms

DOSAGE AND ADMINISTRATION
Usual dose is one or two tablets 3 to 4 times daily as needed for relief of pain when tension or anxiety is present Not recommended for patients 12 years of age and under

OVERDOSAGE:
Treatment is essentially symptomatic and supportive Any drug remaining in the stomach should be removed Induction of vomiting or gastric lavage may be indicated Activated charcoal may reduce absorption of both aspirin and meprobamate Aspirin overdosage produces usual symptoms and signs of salicylate intoxication Observation and treatment should include management of hyperthermia, specific parenteral electrolyte therapy for ketoacidosis and dehydration, watching for evidence of hemorrhagic manifestations due to hypoprothrombinemia which, if it occurs, usually requires whole-blood transfusions Suicidal attempts with meprobamate have resulted in drowsiness lethargy stupor, ataxia coma shock vasomotor and respiratory collapse Some suicidal attempts have been fatal The following data, reported in the literature and from other sources are not expected to correlate with each case (considering factors such as individual susceptibility and length of time from ingestion to treatment) but represent usual ranges reported Acute simple overdose (meprobamate alone) Death has been reported with ingestion of as little as 12 grams meprobamate and survival with as much as 40 grams

BLOOD LEVELS.
0 5-2 0 mg percent represents usual blood-level range of meprobamate after therapeutic doses The level may occasionally be as high as 3 0 mg percent

3-10 mg percent usually corresponds to findings of mild-to-moderate symptoms of overdosage, such as stupor or light coma

10-20 mg percent usually corresponds to deeper coma requiring more intensive treatment Some fatalities occur

At levels greater than 20 mg percent, more fatalities than survivals can be expected

Acute combined overdose (meprobamate with other psychotropic drugs or alcohol) Since effects can be additive history of ingestion of a low dose of meprobamate plus any of these compounds (or of a relatively low blood or tissue level) cannot be used as a prognostic indicator

In cases of excessive doses, sleep ensues rapidly and blood pressure, pulse and respiratory rates are reduced to basal levels Any drug remaining in stomach should be removed and symptomatic treatment given Should respiration or blood pressure become compromised respiratory assistance CNS stimulants and pressor agents should be administered cautiously as indicated Diuresis, osmotic (mannitol) diuresis peritoneal dialysis, and hemodialysis have been used successfully in removing both aspirin and meprobamate Alkalinization of the urine increases excretion of salicylates Careful monitoring of urinary output is necessary and caution should be taken to avoid overhydration Relapse and death, after initial recovery have been attributed to incomplete gastric emptying and delayed absorption

HOW SUPPLIED
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Physicians, Prescriptions and Prescription Drugs

John A. Ewing, M.D.

• *Physicians in North Carolina need to be cautious in their prescribing practices lest they contribute innocently to the State's growing drug dependency problems.*

CHARLESTON, South Carolina was selected for a 1984 AMA-sponsored conference on Prescription Drug Abuse involving representatives from eight southeastern states. I attended on behalf of the North Carolina Medical Society and learned much that I want to share with fellow physicians.

Size of the Problem

Mr. Roy Epps who is Chief of the Regulatory Branch of the North Carolina Department of Human Resources underlined the enormity of the problem when he told us that no less than 100,000 people in North Carolina have legitimate access to controlled substances. Annually, between 125 and 150 drug deaths occur in our State, 90% of these from prescription drug overdose. The "street drugs," such as cocaine and heroin, account for only 10% of such deaths. Those who know estimate that at least two hundred thousand dosage units of drugs are obtained illegally by forgery in North Carolina annually.

Cost of the Problem

Mr. Keith Bulla who is with the Drug Investigative Unit of the State Bureau of Investigation told us that even our blank prescription forms have value to criminals. He had made some interesting calculations. For example, a current problem is the diversion of phenmetrazine hydrochloride (Preludin) to the street. Big money is involved. He finds that, based on current street prices, a person who could persuade a physician to write a prescription for 60 tablets and, by shopping around, could accomplish this five days a week would have a profit of $240,000 at the end of one year. Such criminals exist out there and do come to our offices. One who specializes in hydromorphone hydrochloride (Dilaudid) and who has built up a relationship with a series of physicians can have a lucrative business. Bulla has calculated that such a criminal, seeing each physician approximately every six weeks, need only have duped 18 in order to get three prescriptions weekly for up to 100 Dilaudids. These tablets, on the street, will provide the criminal with an annual income of $780,000 after all expenses are taken care of!

Iatrogenic Drug Dependence

A recent JAMA survey showed that 1.6% of prescriptions involve drugs to combat anxiety that are still being taken by patients as much as seven years after they were originally needed. In some instances we should be educating our patients that drugs are not always the answer. With drug-dependent patients we should be promoting a program of gradual withdrawal.

Diversion

However, diversion of prescription drugs is the greatest problem. In this area, in addition to educating physicians about how they may be used, there are obvious needs for law enforcement.

An ex-criminal and ex-drug addict told us how he became disenchanted with the poor quality of heroin available on the streets of New York. He then became a professional "doctor shopper." To accomplish this he would dress well, be carefully groomed and ready to pay in cash. He said that some "soft touch" doctors were innocent, but could always be good for at least one prescription. He specialized in complaints of lower back pain and simulating the symptoms of a kidney stone. In addition to finding innocent doctors, he began to know of some who were willing to write a prescription for a fee. Another source was the pharmacist who illegally catered to drug abusers. From such sources this drug addict used to purchase Dilaudid tablets for $7.50 each and maintained his own habit by selling these on the street for $25 to $35 each. Again and again he saw physicians reaching for prescription pads after being fooled by him, instead of talking about the real problem of drug dependence and the need for appropriate treatment.

Physician Involvement

Speaker after speaker described the doctor who gets involved in prescription drug diversion as showing some specific characteristics: he may be dated, defiant (of government regulations), disabled, dishonest, distracted, duped, drugged or drunk. Obviously, the issue of the impaired physician is a subject in itself. But too many of us are easily distracted and duped under the pressures of hospital and office practice.

Countermeasures

Although some of the problems call for law enforcement, we as practicing physicians can reduce prescription drug abuse and diversion by exercising care and by seeing that office staff are aware of the problem and what should

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From the Center for Alcohol Studies, UNC School of Medicine, Chapel Hill 27514.

be done. Even blank prescription pads are valuable and should not be left where they can be easily stolen. They should never be used for penciled memoranda or notes that can be erased. The actual amount of medication prescribed should be written out in words as well as in numerals. Pads should not be left in examining rooms, office areas or in bags or cars where they can easily be picked up. Obviously, prescriptions should be written in indelible ink and prescription blanks should never be signed in advance.

Manipulative Patients

Addicts who will try to dupe us will often claim physical problems, particularly illnesses having symptoms of severe pain which are generally treated with narcotics. Some will feign psychological problems, complaining of insomnia, fatigue, depression, anxiety or stress when stimulant drugs or depressants are desired rather than analgesics. Some will use deception including theft, forgery or alteration of prescriptions, often requesting refills prematurely. They will claim that the medicine was lost or stolen. Some have been described as even employing coercive tactics such as threats of physical or financial harm, bribery, or citing influential families or friends to obtain the medications they desire. Common characteristics of drug-seeking behavior include dramatic but vague complaints; subjective complaints without confirming objective signs; presentation of a self-diagnosis and naming of a specific medication desired; showing no interest in confirming a diagnosis or undertaking other forms of treatment and showing lack of interest in keeping appointments for referrals or diagnostic tests. When encountering such a patient we should maintain a strong professional control of the situation and look upon him or her as having a serious illness, namely, drug dependence. Discussing specialized treatment programs is indicated.

Plans in North Carolina

During the meeting in Charleston each state had caucuses to discuss state-wide responses to the problem of prescription drug diversion. Acting as spokesman for the North Carolina group, Mr. Steven L. Hicks, Deputy Director of Alcohol and Drug Abuse Services in the Department of Human Resources has recommended to Governor Hunt the appointment of a 15 member steering committee to address the problem. We hope such a committee will plan a North Carolina Conference on Prescription Drug Abuse, will discuss appropriate responses to the impaired professional who is contributing to the problem of drug diversion, will use the media to stimulate public awareness of the problem, and will focus on the education and training of professionals who can contribute their share to reducing the problem of drug diversion.

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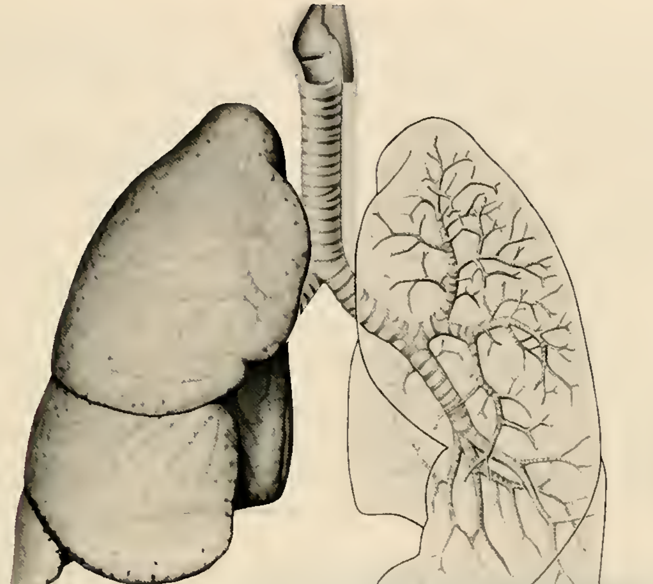

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Brief Summary Consult the package literature for prescribing information

Indications and Usage Ceclor* (cefaclor Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms

Lower respiratory infections including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae), Haemophilus influenzae* and *S pyogenes* (group A beta-hemolytic streptococci)

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor

Contraindication Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics

Warnings IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS INCLUDING ANAPHYLAXIS TO BOTH DRUG CLASSES

Antibiotics including Ceclor should be administered cautiously to any patient who has demonstrated some form of allergy particularly to drugs

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides semisynthetic penicillins, and cephalosporins), therefore it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics Such colitis may range in severity from mild to life-threatening

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies and fluid electrolyte and protein supplementation When the colitis does not improve after the drug has been discontinued or when it is severe oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C difficile* Other causes of colitis should be ruled out

Precautions *General Precautions* — If an allergic reaction to Ceclor* (cefaclor, Lilly) occurs the drug should be discontinued, and if necessary the patient should be treated with appropriate agents e g pressor amines antihistamines, or corticosteroids

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms Careful observation of the patient is essential If superinfection occurs during therapy appropriate measures should be taken

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs test may be due to the drug

Ceclor should be administered with caution in the presence of markedly impaired renal function Under such conditions careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended

As a result of administration of Ceclor a false-positive reaction for glucose in the urine may occur This has been observed with Benedict s and Fehling s solutions and also with Clinitest*, tablets but not with Tes-Tape* (Glucose Enzymatic Test Strip USP Lilly)

Broad spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis

Usage in Pregnancy — Pregnancy Category B — Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor* (cefaclor Lilly) There are however, no adequate and well-controlled studies in pregnant women Because animal reproduction studies are not always predictive of human response this drug should be used during pregnancy only if clearly needed

Nursing Mothers — Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses Average levels were 0 18, 0 20, 0 21, and 0 16 mcg/ml at two three, four, and five hours respectively Trace amounts were detected at one hour The effect on nursing infants is not known Caution should be exercised when Ceclor is administered to a nursing woman

Usage in Children — Safety and effectiveness of this product for use in infants less than one month of age have not been established

Adverse Reactions. Adverse effects considered related to therapy with Ceclor are uncommon and are listed below

Gastrointestinal symptoms occur in about 2 5 percent of patients and include diarrhea (1 in 70)

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment Nausea and vomiting have been reported rarely

Hypersensitivity reactions have been reported in about 1 5 percent of patients and include morbilliform eruptions (1 in 100) Pruritus urticaria and positive Coombs' tests each occur in less than 1 in 200 patients Cases of serum sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and frequently fever) have been reported These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor Such reactions have been reported more frequently in children than in adults Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy No serious sequelae have been reported Antihistamines and corticosteroids appear to enhance resolution of the syndrome

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients)

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported Although they were of uncertain etiology they are listed below to serve as alerting information for the physician

Hepatic — Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40)

Hematopoietic — Transient fluctuations in leukocyte count predominantly lymphocytosis occurring in infants and young children (1 in 40)

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200)

[061782R]

Note Ceclor* (cefaclor Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections including the prophylaxis of rheumatic fever See prescribing information

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IN STATE

October 13-14
Radiology Mini-Course in Abdominal Imaging
Place: Durham
Credit: 10 hours Category I AMA
Info: Cindi Easterling, Box 3108, Duke University Medical Center, Durham 27710. 919/684-6878

October 17
Symposium on Critical Care
Place: Gastonia
Info: Linda Mauldin, Gaston Memorial Hospital, 2525 Court Drive, Gastonia 28052

October 17
Update on Hepatitis
Place: Sanford
Credit: 2 hours Category I AMA and AAFP
Info: R. S. Cline, M.D., Central Carolina Hospital, 1135 Carthage Street, Sanford 27330. 919/774-6518

October 24-27
Fall Seminar, American Academy of Clinical Anesthesiologists
Place: Asheville
Credit: 11 hours Category I AMA
Info: AACA, Knoxville, TN 37919-1691. 615/588-6279

October 26-27
Psychopharmacology: Practical Drug Treatment of Psychiatric Disorders
Place: Chapel Hill
Credit: 10 hours Category I AMA
Fee: $125
Info: Nancy Williams, Department of Psychiatry, UNC School of Medicine, Chapel Hill 27514. 919/966-4738

October 26-27
Advanced Cardiac Life Support Instructors Course
Place: Winston-Salem
Credit: 20 hours Category I AMA and ACEP
Fee: $250
Info: Earl Schwartz, M.D., Emergency Medicine, Bowman Gray School of Medicine, Winston-Salem 27103.

November 1-2
Current Topics in Urology
Place: Chapel Hill
Credit: 13 hours Category I AMA
Fee: $125
Info: Barbara Judd, 428 Burnett-Womack Building 229H, Chapel Hill 27514. 919/966-2571

November 7
Update: Infant Psychiatry
Place: Winston-Salem
Info: Child Guidance Clinic, Inc., 1200 Glade Street, Winston-Salem 27101. 919/723-3571

November 11-14
Advanced Clinical Teaching Skills
Place: Rougemont
Credit: 20 hours Category I AMA and AAFP
Info: Katherine Munning, 407 Crutchfield Street, Durham 27705. 919/471-2571

November 28
Obstetrical Analgesia/Anesthesia
Place: Sanford
Credit: 2 hours Category I AMA and AAFP
Info: R. S. Cline, MD., Central Carolina Hospital, 1135 Carthage Street, Sanford 27330. 919/774-6518

December 4
Duke Tuesday
Place: Durham
Credit: 5 hours Category I
Info: Linda Mace, Box 3707, Duke University Medical Center, Durham 27710. 919/684-2033

December 5
Tourette's Syndrome
Place: Winston-Salem
Info: Child Guidance Clinic, Inc., 1200 Glade Street, Winston-Salem 27101. 919/723-3571

OUT OF STATE

October 12
Selected Topics in Pediatrics
Place: Norfolk, VA
Info: Jean E. Shelton, M.D., Children's Hospital of the King's Daughters, 800 West Olney Road, Norfolk, VA 23507. 804/628-3798

October 12
New Guidelines for Management of Non-insulin Dependent Diabetes
Place: Richmond, VA
Info: Kay Parrott, Box 48 MCV Station, Richmond, VA 23298. 804/786-0494

October 18-25
Review of Clinical Chemistry Seminar
Place: San Diego, CA
Credit: 40 hours Category I AMA
Fee: $315
Info: Mary Valand, Box 7224, ECU School of Medicine, Greenville 27834. 919/758-5200

October 20
Medical Malpractice Risk Management
Place Williamsburg, VA
Info: Kathy Martin, Box 48 MCV Station, Richmond, VA 23298. 804/786-0494
Fee: $75

October 20-27
4th Diving Accident and Hyperbaric Oxygen Treatment
Place: Grand Cayman, BWI
Credit: 26 hours Category I AMA, AAFP, ACEP
Info: Cindi Easterling, Box 3108, Duke University Medical Center, Durham 27710. 919/684-6878

October 22-26
Postgraduate Course in Diagnostic Imaging
Place: Bermuda
Credit: 25 hours Category I AMA
Fee: $495
Info: Jacqueline D. Wright, Box 3808, Duke University Medical Center, Durham 27710. 919/681-2711

November 2-3

Fifth Annual G.I. Assistant: Principles and Practice
Place: Richmond, VA
Fee: $95
Info: Kathy Martin, Box 48 MCV Station, Richmond, VA 23298. 804/786-0494

November 13

Divorce, Child Custody and the Family
Place: Johnson City, TN
Info: Sue Hutchinson, Quillen-Dishner College of Medicine, Johnson City, TN. 615/928-6426, ext. 204

November 14-17

Williamsburg Symposium on Perinatal Care
Place: Williamsburg
Credit: 12 hours Category I
Fee: $200
Info: Mary Valand, Box 7224, ECU School of Medicine, Greenville 27834. 919/758-5200

November 16

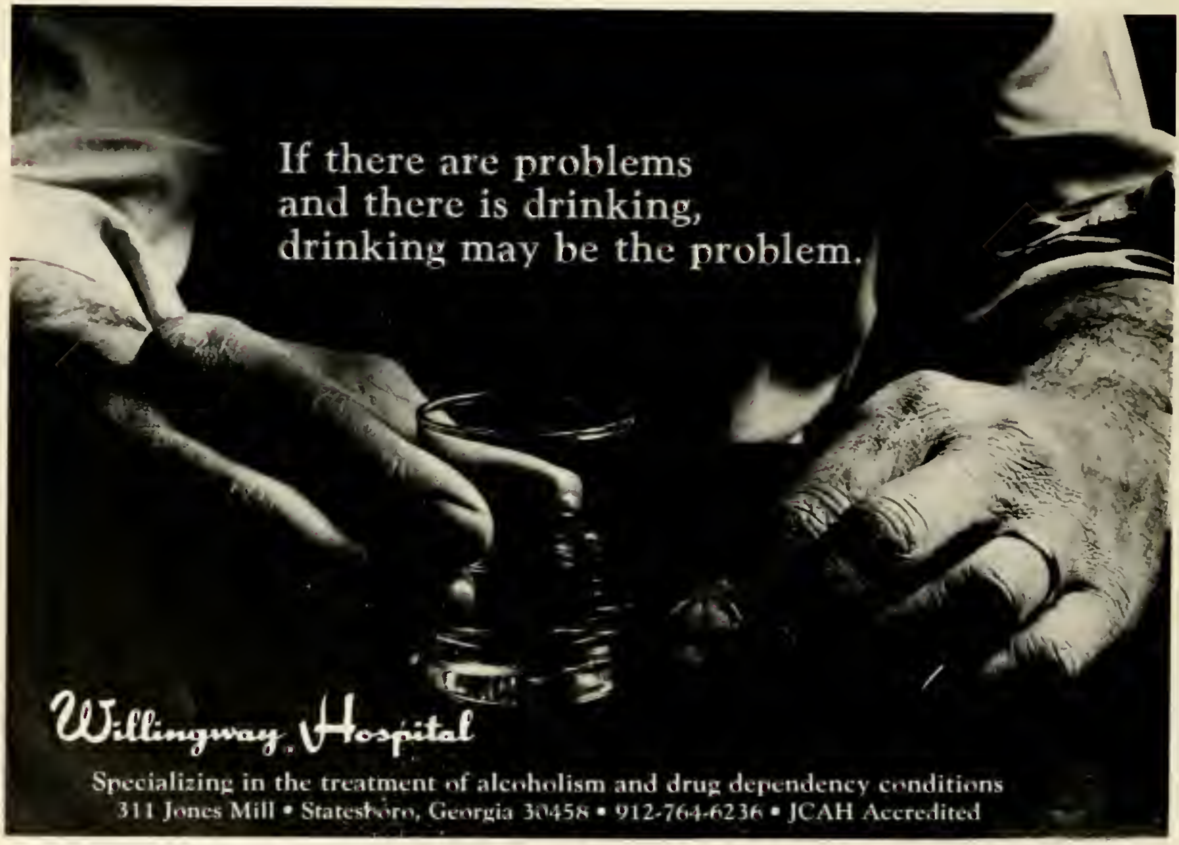
Update: Sudden Infant Death Syndrome
Place: Richmond, VA
Fee: $95
Credit: 7 hours Category I AMA, PREP, ACOG, AAFP
Info: Beth Winn, Box 48 MCV Station, Richmond, VA 23298. 804/786-0494

December 6-15

Review of Clinical Chemistry Seminar
Place: Snowmass, CO
Credit: 40 hours Category 1
Fee: $315
Info: Mary Valand, Box 7224, ECU School of Medicine, Greenville 27834. 919/758-5200

Physicians Without Partners

A support group among divorced physicians is being formed. The first meeting will be in early October at the Center for Professional Well-Being, 5102 Chapel Hill Boulevard, Durham 27707. Phone: 919/489-9167. Physicians have unique issues to resolve in divorce. This group is being formed to provide a forum for discussion of the problems and feelings they confront. There will be a nominal fee.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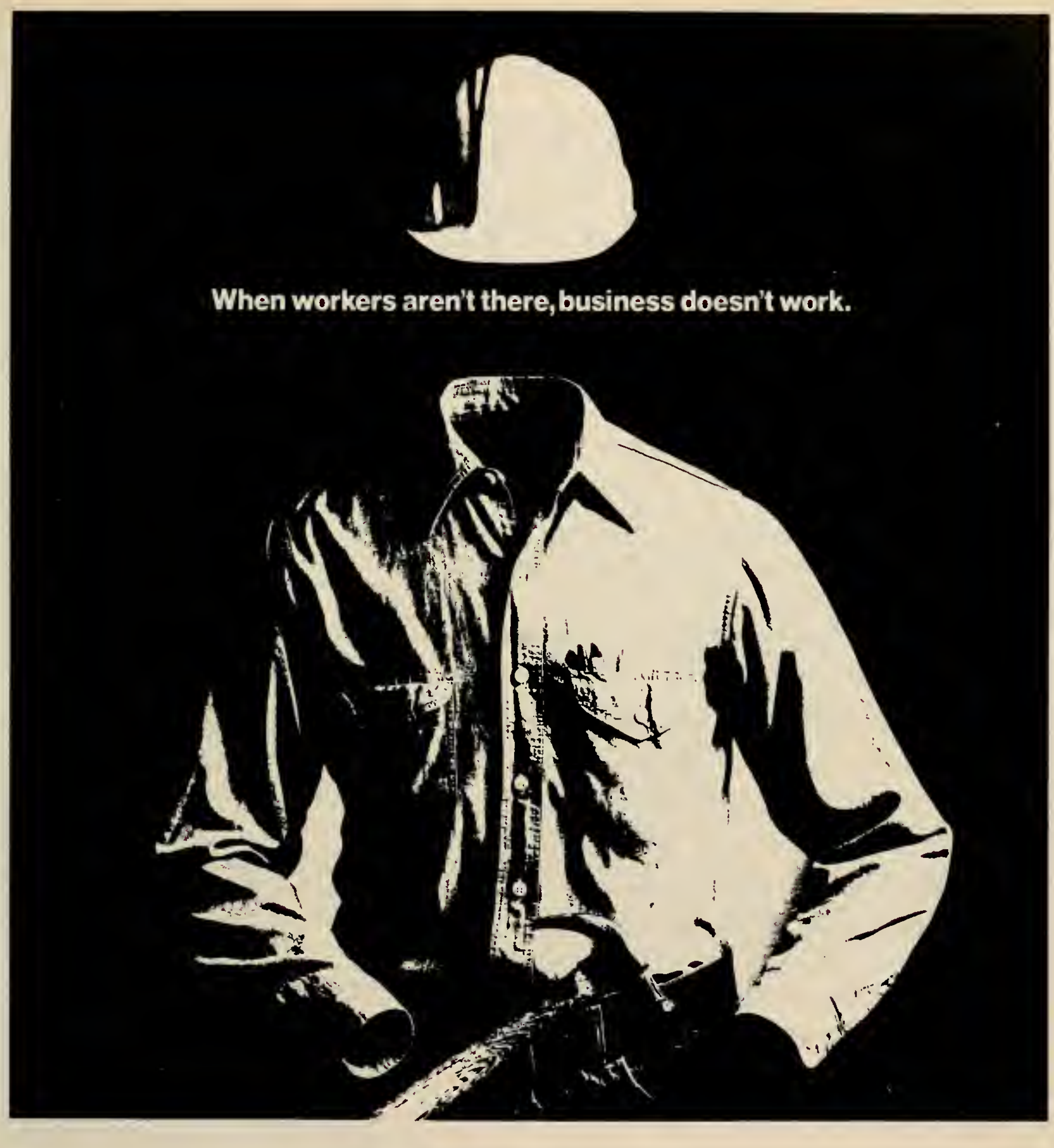

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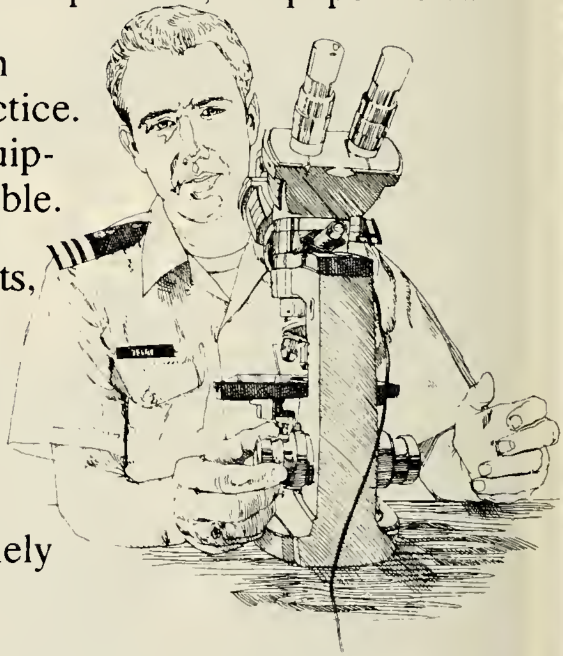

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Before prescribing, see complete prescribing information in SK&F CO. literature or *PDR*. The following is a brief summary.

* **WARNING**
This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K^+ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K^+ intake. **Associated widened QRS complex or arrhythmia requires prompt additional therapy.** Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function.

Thiazides may add to or potentiate the action of other antihypertensive drugs.

Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth; anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions; nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances, postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

Supplied: 'Dyazide' is supplied in bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak™ unit-of-use bottles of 100.

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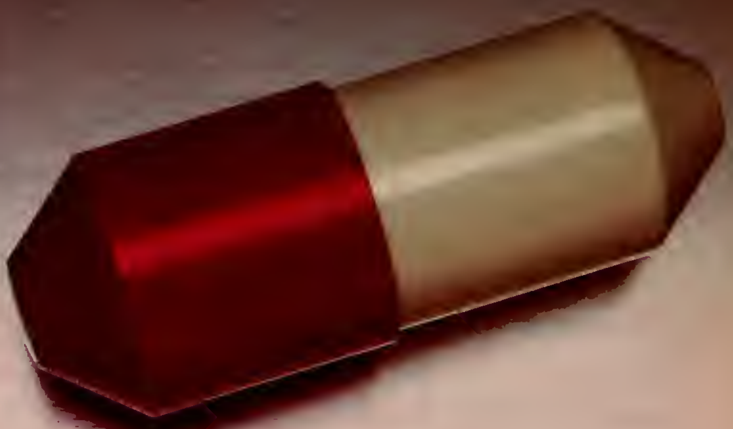

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Letters to the Editor

Where Have All the Funtimes Gone?

I am a real fan of Ann Landers and read her column regularly. I have followed with particular interest the controversy concerning the working conditions of the housestaff in our teaching hospitals. This began several months ago with a letter from the mother of a resident physician deploring the exploitive nature of our training programs. She was particularly critical of the long periods on call which she felt left her son exhausted and unable to function adequately. A series of letters followed which either defended or attacked the system. One of these letters was from Dr. Jay Arena, professor emeritus of pediatrics at Duke University Medical Center, concerning his training years. Dr. Arena wrote, "Except for missing my wife, these were the happiest years in my life despite long hours, demanding responsibilities and almost nonexistent salary."

What Dr. Arena was saying was that the enjoyment of practicing medicine compensated for the lost sleep, limited social life, and even the lack of a living wage — quite a tribute to something so nebulous as "the joy of medicine."

I, too, found the years of residency training to be happy and rewarding ones, despite being paid almost as meagerly as Dr. Arena. What is the difference between now and then? Is the fun in medicine still there or have things changed so radically that the joy has been all but squeezed out?

Looking back thirty plus years, it seems to me that the basis of my satisfaction in those days was to finally be able to do the job that I wanted to do along with a group of people whom I liked and respected. During those housestaff years there was a spirit of camaraderie which accompanies a group of people who are working together toward a worthwhile goal. It can be compared with the spirit of the television series "MASH." There conditions were rotten, the job hours incredibly long, the work stressful and dangerous, but the spirit of cooperation toward the ultimate aim of saving the lives and limbs of our servicemen made it all worthwhile. At my residency hospital, it was fun to meet with friends in the dining room and discuss your interesting cases or the latest clinical pearl dropped on rounds or the goofs made by your rounding man, intern, or even yourself. There was a good deal of one-upmanship but this was largely carried out in a spirit of friendly jousting intended to stimulate rather than stifle your eagerness. In fact, probably more medical know-how was acquired at these impromptu sessions than at more formal rounds and conferences. The nights spent in the grim call rooms were usually compensated for by the challenge of managing that diabetic in acidosis or the patient in the emergency room with acute pulmonary edema. You might be tired and bored as you shifted from foot to foot on the third hour of ward rounds, but somehow you were aware that what you were doing was important and that you were being educated in the best sense of the word.

The rigors of the period were softened by the laughter. The young intern leaning over the bed of the lady who was unconscious from an overdose. "What did you take?" he shouts in her ear. No response. "What was the name of the medicine?" Only heavy breathing in answer. In desperation, louder, precisely articulated, "Was it a BAR-BIT-U-RATE?" Finally, a sluggish arousal. "NO, SECONAL." Or the morning report of the junior residents to the Chief of Medicine, a much respected physician and role model. While giving the report of the previous night's admissions, one of the housestaff notes that the Chief has on one brown and one blue sock. While others report, he agonizes as to whether to mention this to the Chief. At the end of report, he decides to do so. "You have one blue sock and one brown sock on, Sir." The cool response, "That's all right, John, I have another pair just like it at home." One morning, reporting to Dr. Eugene Stead about a physical finding on a patient: "Dr. Spleen, the stead was palpable." This is the glue which holds the pieces together.

As I look over my years of practice, I feel fortunate to be a part of this great profession and to have been able to grow and change with the times. I am especially appreciative of the opportunity to associate with my colleagues, men and women of the highest intellectual and moral character. We physicians quite naturally envision our relationship with our patients as a one-directional outflow of medical education, support, diagnosis and treatment — from us to them. The longer I am in the business, however, the more I realize that it is indeed a two-way street and that I have learned immeasurably from my patients. I am not talking about disease, but rather the numerous examples of human courage, fortitude, and sacrifice — the families who have given up all semblance of normal routine and livelihood to remain at the bedside day after day, night after night, ministering to a loved one — the sharecropper's wife who, through her strength of will and good sense, pulled her family through devastating economic and social hardship — the professor who for years cared for his wife, bedridden with multiple sclerosis — the vigorous, intelligent, witty ninety year old lady, who, when it was obvious that her life was fast fading, had one request of me, her physician, "Let me go, let me go." I often wonder if I could have tolerated the series of life's blows which I have watched my patients sustain and survive.

Changes there certainly have been over the years. The amount of information to be assimilated has exploded. The government has increasingly injected itself between doctor and patient. Housestaff members are now married, many have children, and therefore, have a divided loyalty. The intensive care units are keeping patients alive who, in my day, would have died. Their lives are sustained with minute-to-minute decisions on changes in dial settings and IV drug injections. Certainly, this increases the level of stress for the resident. Little seems to be left to the "Will of God" — everything seems to be up to our proper manipulations.

Despite the changes, the basic attraction of a career in medicine is still there — the interaction of one human being with another, and especially the privilege of ministering to the needs of another individual.

Where have all the funtimes gone? Nowhere, they're still very much alive.

Robert W. Willett, M.D.
2800 Blue Ridge Boulevard
Raleigh 27607

The editor remembers his first contact with Bob Willett. Sam Martin, the first chief resident I appointed at Duke and an excellent appraiser of talent, stopped me in the hall and asked me to accompany him to the resident's office. He had collared an outstanding third-year student and he hoped to persuade him to take his internship at Duke. I was equally impressed, and Bob more than measured up to our expectations. In one way, he went beyond. He was smart enough to persuade Hilda Pope, a budding bacteriologist, to marry him.

eas

Warmth Treatment of Nasal Obstruction Due to Antihypertensive Medicines

To the Editor:

I am a retired physician. I take medicines to control high blood pressure and gout. As a side effect of these medicines, I have had a continuing problem with nasal obstruction and infection. The problem has been worse in the winter than during milder weather.

Recently, I found that staying warm gave relief. If my nose is bothering me, I turn on the electric blanket and crawl into bed. Warming the legs and trunk is not a cure, but it does lessen the misery. Soon I feel better.

Of course, I know that using surface warmth as therapy is not original or any big discovery. But if you had spent as many restless nights as I have, and finally had found something simple which helped you breathe through your nose, you might be pleased. You also might regard this therapy as an improvement and want to share it with others.

Have any of our practicing profession made similar observations?

Albert D. Warshauer, M.D.
1608 East 5th Street
Greenville 27834

Kudos

To the Editor:

Just a brief word to tell you how much the men in our group, including myself, think the journal has improved since you have taken over at the helm. Please keep up the good work.

Austin T. Hyde, Jr., M.D.
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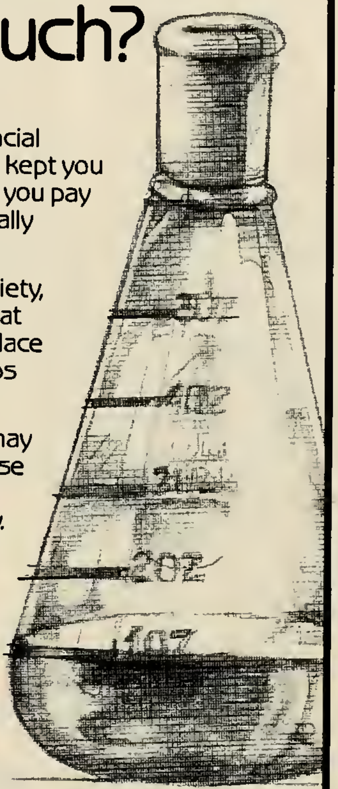

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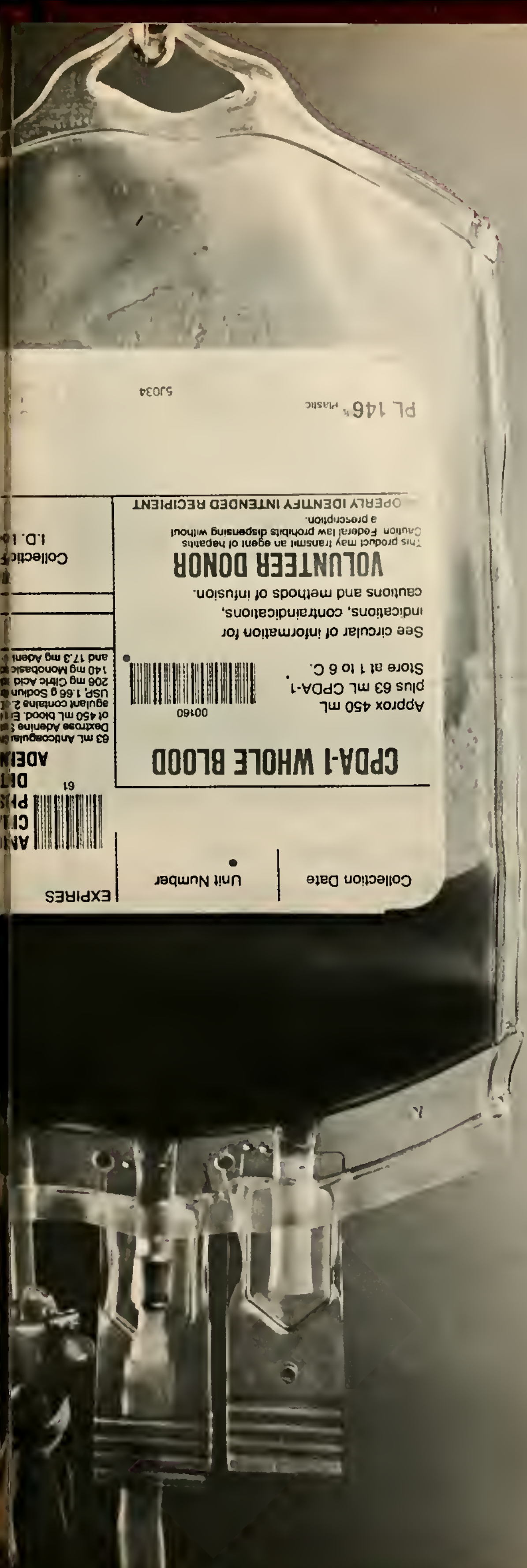

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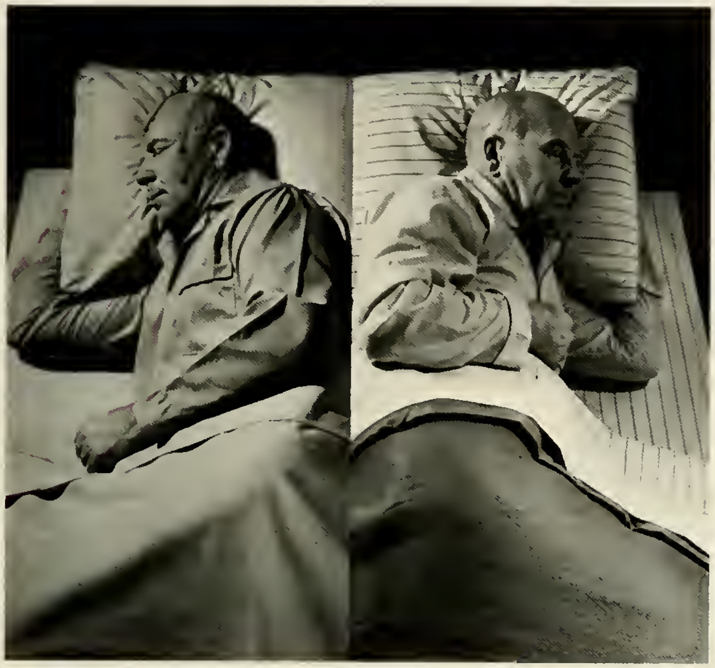

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References: 1. Kales J *et al: Clin Pharmacol Ther* 12:691-697, Jul-Aug 1971. **2.** Kales A *et al: Clin Pharmacol Ther* 18:356-363, Sep 1975. **3.** Kales A *et al: Clin Pharmacol Ther* 19:576-583, May 1976 **4.** Kales A *et al: Clin Pharmacol Ther* 32:781-788, Dec 1982. **5.** Frost JD Jr, DeLucchi MR: *J Am Geriatr Soc* 27:541-546, Dec 1979. **6.** Kales A, Kales JD: *J Clin Pharmacol* 3:140-150, Apr 1983. **7.** Greenblatt DJ, Allen MD, Shader RI: *Clin Pharmacol Ther* 21:355-361, Mar 1977 **8.** Zimmerman AM. *Curr Ther Res* 13:18-22, Jan 1971. **9.** Amrein R *et al: Drugs Exp Clin Res* 9(1):85-99, 1983. **10.** Monti JM: *Methods Find Exp Clin Pharmacol* 3:303-326, May 1981. **11.** Greenblatt DJ *et al: Sleep* 5(Suppl 1):S18-S27, 1982. **12.** Kales A *et al: Pharmacology* 26:121-137, 1983.

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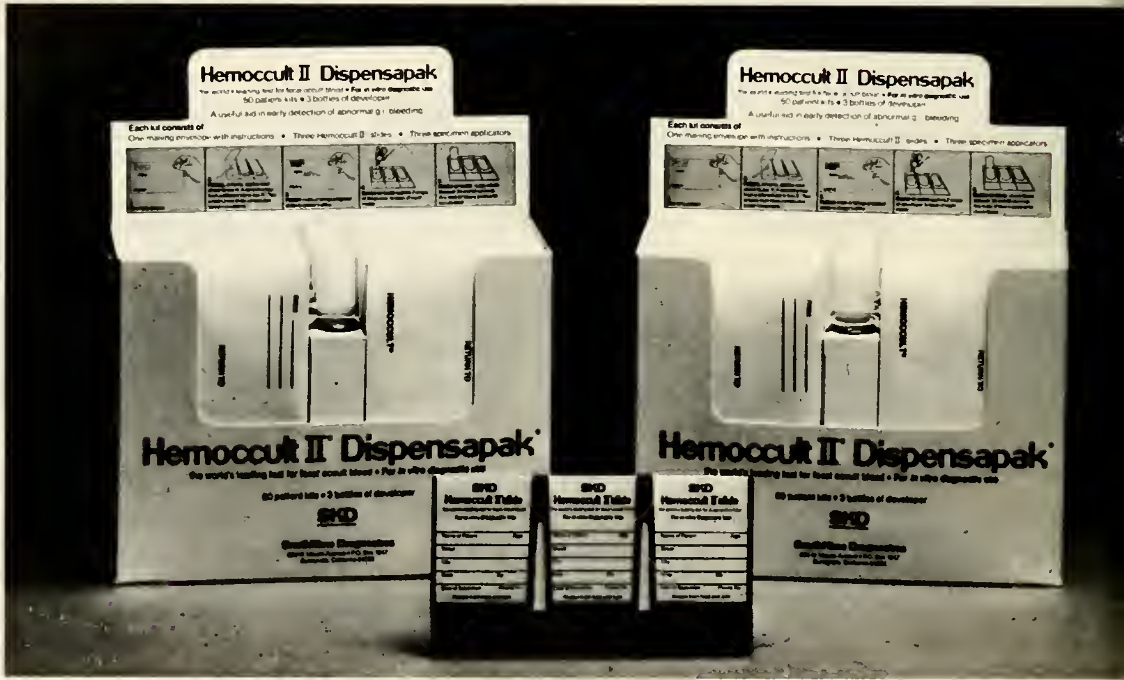

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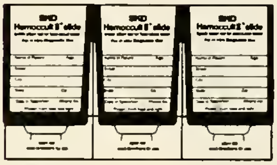

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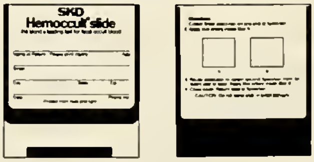

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ntroduction

J. Proctor, M.D.

● *Introductory comments by the editor of this issue on trauma care in North Carolina.*

T is indeed a pleasure to serve as unofficial "guest"
editor for this issue of the *North Carolina Medical*
urnal devoted to trauma. Since 1962 when I was a
rgical intern at the North Carolina Memorial Hospital, I
ve had a unique opportunity to observe and participate in
evolution of trauma care in North Carolina. From 1962
ien the emergency *room* was often referred to as the
it," seldom frequented by senior staff members, has
me the specialty of emergency medicine, the American
llege of Emergency Physicians, and the creation of the
dern emergency *department* which has assumed a legiti-
ite place in the hospital administrative hierarchy. Trauma
tims are now delivered to emergency departments by
ll-trained EMTs or paramedics in well-equipped ambu-
ices rather than by individuals with 26 hours of American
d Cross first aid using a hearse as a conveyance. The
fice of Emergency Medical Services, categorization of
spitals, designation of trauma centers, standardized
nsfer protocols, radio communications and upgrading of
bulances have all evolved, enabled in large part by a
eficent legislature with a willingness to fund statewide
grams and a willingness on the part of local govern-
nts to provide matching funds.

n this issue of the *North Carolina Medical Journal*
ch of the above progress is chronicled by Tom Harme-
, Chief of the North Carolina Office of Emergency
dical Services. There have been three Level I statewide
ima centers designated in North Carolina and a description of some of the activities of the University of North Carolina-North Carolina Memorial Statewide Trauma Center is included as an illustrative example along with articles illustrating specialized problems relating to orthopaedic injuries (Laurence Dahners, M.D.), and the approach to central nervous systems injuries (Michael Rosner, M.D.).

Several Level II trauma centers have also been designated. Frequently located with more rural surroundings, their unique problems in patient access, transportation, and emergency department care are addressed by Larry Lewis, M.D. of the Department of Surgery, East Carolina University.

A major mission of statewide trauma centers involves outreach educational programs. The two statewide trauma centers located at the University of North Carolina and Duke University have combined to develop and present such an educational program for physicians and nurses in community hospitals, described in this issue by Joseph Moylan, M.D., Chief of the Trauma Service at Duke University Medical Center. The North Carolina Committee on Trauma of the American College of Surgeons has been an extremely active professional organization as the article by Dr. Robert Youngblood illustrates. The Highway Safety Research Center, a part of the University of North Carolina Statewide Trauma Center, has been active in motor vehicle safety standards and the article by B. J. Campbell should be particularly interesting for the lay reader as well as the professional.

North Carolinians can be justly proud of the progress made in trauma care in North Carolina, where trauma is *not* "the forgotten disease of modern society."

---

m the Trauma Section, Department of Surgery, University of North
olina School of Medicine, Chapel Hill 27514.

SCIENTIFIC ARTICLE

Emergency Medical Services in North Carolina

Thomas M. Harmelink

- *A history of EMS since 1966 – in North Carolina from 1973 to the present.*

TEN years ago it was referred to as ambulance services — today it is known as emergency medical services or more commonly as EMS. This change in terminology is symbolic of the significant developments that have taken place in the delivery of emergency medical care to the critically ill and injured. The emphasis today is on the establishment of a medical care delivery system and not simply on a transportation system offering a fast ride to the hospital.

The report, "Accidental Death and Disability — The Neglected Disease of Modern Society," issued in 1966 by the National Academy of Sciences-National Research Council is generally credited with bringing the nation's attention to the needless loss of life resulting from inadequate or absent emergency medical care systems. To some extent the problem is still as critical. Accidents are the fourth leading cause of death in North Carolina, as is the case for the entire United States, and the number one killer of those under the age of 35. The leading cause of death is heart disease, which claimed over 17,000 lives in North Carolina in 1982, over half of which can be attributed to acute myocardial infarction. These two major problems, along with many other critical illnesses, are being addressed through efforts at the state, regional, and local levels to establish emergency medical services systems.

Background and Structure

In North Carolina, activity was precipitated by the Emergency Medical Services Act of 1973 which established a statewide emergency medical services program. The Office of Emergency Medical Services was created in the Department of Human Resources and identified as the lead state agency for EMS activities. It was assigned regulatory responsibilities typical of those one comes to expect of a government agency, such as the certification of ambulance personnel and the inspection of ambulances. But, more importantly, it was given broader mandates to promote, encourage, and assist in the development of statewide, regional, and local emergency medical services programs. Along with the mandates came funding from the General Assembly to support the operational and developmental aspects of the program.

The legislation calls for an Emergency Medical Services Advisory Council to advise the Secretary of the Department of Human Resources on all matters pertaining to EMS. The Council is composed of representatives from paid ambulance providers, volunteer rescue squads, hospitals, loc government, nursing, the medical community, the gene public, and the state legislature. Early on, the Coun adopted the following philosophy for the program whi remains valid today:

(1) to foster regional services which are designed a operated in accordance with local initiative, regional nee and statewide standards and guidelines; and

(2) to provide supportive statewide programs to ensu that every medical provider is well trained, every emerge cy vehicle well equipped and properly operated, all comp nents connected by effective communications, and eve citizen within reach of high quality emergency medic care.

Basic to this philosophy and, thus, to the state E program, is the regional approach to establishing a comp hensive EMS system. Eighteen regions have been iden fied and a regional EMS council established in each coordinate and develop the system on this level (figure Each council is affiliated with the Lead Regional Organiz tion (a council of governments or planning and econon development commission) in its region and has a me bership similar to that of the State EMS Advisory Counc They are funded primarily by state funds and are respon ble for identifying regional needs, establishing prioriti within the region for funding, developing a regional E plan, planning and implementing regionwide projec serving as a forum for resolving problems within th region and, in general, coordinating EMS activities.

The responsibility for providing ambulance service re at the local level and, for all practical purposes, resides w the county government. Virtually all counties provide so level of funding to the ambulance services within th jurisdiction, usually in the form of direct operating costs subsidies to volunteer and commercial providers. Howe er, their actual involvement varies considerably, rangi from those who provide the service directly through county ambulance service to those who take a much mo passive, almost laissez-faire, approach. Evidence th county governments have realized a need to assert so control and influence over this public service is reflected the fact that 30 have now enacted franchise ordinances regulate EMS activity within the county and 52 have desi nated a county EMS director. Fewer, 16, have formal recognized the importance of considering more than ju the ambulance service by establishing a local EMS coun to coordinate all of the elements of the EMS system on countywide basis. The types of organizations providi ambulance service have changed significantly since t

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From the Office of Emergency Medical Services, Department of Human Resources, Raleigh 27605.

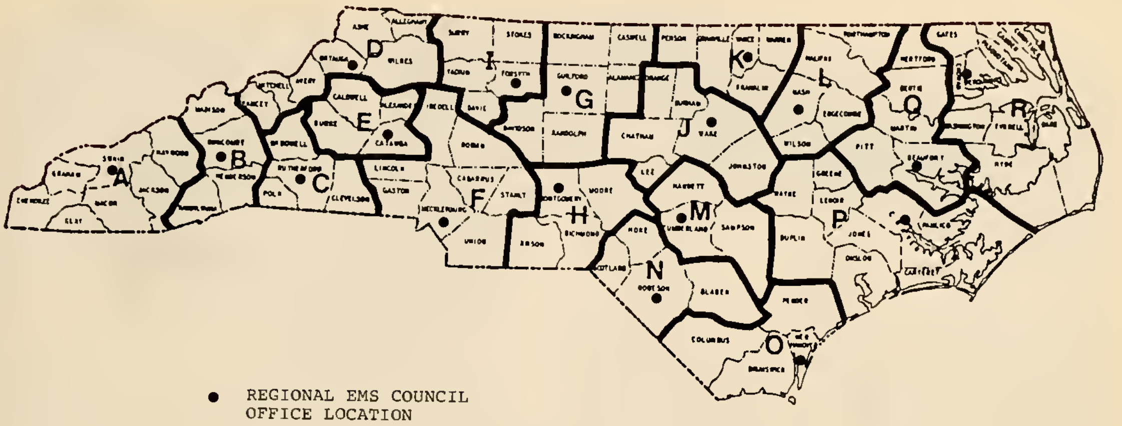

Figure 1. *Emergency medical services regions, June 1984.*

early 1970s as shown in table 1. In terms of numbers, most notable is the increase in the number of volunteer rescue squads from 205 in 1972 to 377 in 1984 to where they now comprise 73 percent of all providers versus 51 percent in 1972. To a large extent, they organized to fill the gap left by the departure of funeral home operators from the ambulance business. Funeral homes now make up less than 1 percent of the total. Also significant is the increase in government operated ambulance services mainly reflecting the commitment of local governments to ensure that EMS is provided to their community. Another trend resulting from the increased demand for EMS is the addition of paid personnel to volunteer rescue squads primarily to staff the service during the daytime hours. Some 23 of the 377 volunteer rescue squads have at least one paid EMT.

Systems Development

As with most aspects of health care, there are variations in the level of prehospital emergency medical care available across North Carolina. These can be broadly classified into two categories, basic life support and advanced life support, which can serve as a useful measure of the degree to which the EMS system, as a whole, is developed within a county and within a region. Basic life support refers to the provision of prehospital emergency care by personnel, such as EMTs, trained to perform emergency first aid and stabilization. The initiation of definitive treatment at the scene by personnel receiving orders from a physician in a sponsoring hospital is termed advanced life support (ALS). There are two levels of ALS in North Carolina (also referred to as mobile intensive care): (1) EMT-intermediate where the field technicians can start intravenous therapy and insert an esophageal obturator or esophageal gastric tube airway; and (2) EMT-paramedic in which they perform a wide range of medical procedures including the administration of certain drugs, defibrillation, and intubation.

Table 1

Types of Ambulance Service Organizations

	1972 No.	1972 Percent	1984 No.	1984 Percent
Funeral homes	105	26	4	—
Volunteer rescue squads	205	51	377	73
Governmental	24	6	67	13
Commercial	28	7	18	4
Hospital	12	3	19	4
Police and fire	24	6	15	3
Other	4	1	14	3
Totals	402	100	514	100

One of the early goals of the state EMS program was to ensure that basic life support services were provided statewide by personnel trained and certified as EMTs. This has been attained, and all ambulances operating in the state are staffed by at least one certified EMT. In achieving this basic minimum, the focus has shifted from providing transportation to the hospital to responding to the scene with well-trained personnel who can render immediate lifesaving care, stabilize the victim and then transport him safely to the hospital for definitive treatment. The lack of integration of basic life support services and their personnel into the medical care system, i.e., involvement with the medical community and the hospital, while significantly improved, continues to be an area of major concern.

As of June 1984, 47 counties have progressed beyond the basic level and provide advanced life support services to their citizens. Of these, 28 function at the EMT-intermediate level and 19 at the EMT-paramedic level (figure 2). Advanced life support programs cover 72 percent of the state's population, but only 40 percent of the geographical area. Further analysis shows that EMT-paramedic services are available to 32 percent of the population while EMT-intermediate services are provided to 40 percent. These figures point out that ALS programs have been largely established in the more populous counties which are most likely to have paid ambulance services. However, two counties with volunteer services are EMT-paramedic (Haywood and Orange) and were among the first in the state to achieve that status. In terms of ambulance providers, 22 — 17 paid and 5 volunteer — have personnel trained and functioning as EMT-paramedics and

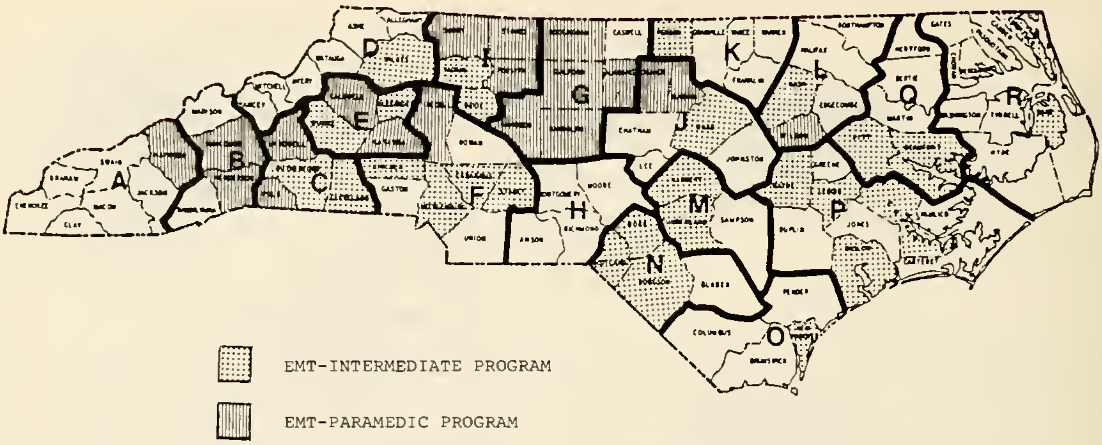

Figure 2. *Advanced life support programs, June 1984.*

53 — 23 paid and 30 volunteer — have personnel trained as EMT-intermediates. More rural counties and volunteer providers are realizing that the EMT-intermediate level is reachable and, in recent years, have made the commitment to upgrade their service to that level.

Training

Progress in North Carolina's EMS program has been most visible in the training of ambulance personnel (table 2). This can be attributed to the fact that it was one of the most deficient aspects of emergency care in the state and, consequently, has been the focus of the Office of Emergency Medical Services' efforts and resources, especially early on. The emergency medical technician training program has been established as the basic standard for ambulance personnel in the state, as it is nationally, raising the minimum training requirements from 30 hours to 81 hours. In reality, however, the average EMT course runs 110-120 hours which is consistent with the latest version of the National Standard EMT Curriculum. State statutes and regulations still recognize a category of certified ambulance attendant, requiring 40 hours of training. There are few ambulance attendants in comparison with EMTs, and most ambulances are staffed with a minimum of two EMTs. Prior to 1974, there were only a handful of EMTs in North Carolina, while in 1984 there are 16,028 holding current certification from the Office of Emergency Medical Services. An estimated 50,000 persons have now taken the EMT training course which is offered through the community colleges. Unique among health professionals, and a point of continuing controversy, particularly among many of the volunteers, is the requirement to take a state examination and be recertified every two years.

Table 2
Certified EMS Personnel

	1977	1980	1984
Ambulance attendants	1,937	1,956	2,308
Emergency medical technicians	12,757	17,873	16,028
EMT-Intermediates	212	539	1,157
EMT-Paramedics	37	159	469
Mobile intensive care nurses	13	319	326
Totals	14,956	20,846	20,288

North Carolina has two categories of ambulance personnel beyond the basic EMT — the EMT-intermediate and the EMT-paramedic — both of which are certified by the Board of Medical Examiners. Presently, there are 1,157 certified EMT-intermediates and 469 certified EMT-paramedics in the state. Most training at these levels takes place through local hospitals which serve as sponsors for advanced life support programs. However, five community colleges have established two-year associate degree programs in emergency medical science. Persons graduating from these programs not only have the clinical training and skills qualifying them for certification as EMT-paramedics, but they have had course work in business, psychology, and other areas to enhance their upward mobility in the system. Graduates of these programs serve as an important manpower pool for EMS services statewide, particularly those at the advanced life support levels.

Recognizing the need to train today's EMS managers, the EMS Management Institute was established in 1982 at the University of North Carolina at Charlotte. This is an intense continuing education program conducted over a nine-month period aimed at upgrading the management skills of the practicing EMS manager. Some 40 persons have now successfully completed this program.

Training programs have also been established for hospital emergency department personnel. Under a grant from the Department of Health, Education and Welfare, the Office of Emergency Medical Services established the Emergency Nurse Education Program with the purpose of upgrading the skills and knowledge of the ED nurse. Before funding expired in 1982, over 290 nurses went through this course. The program was subsequently reformatted into modules and can be offered as a continuing education program by an area health education center or an individual hospital. Also, 326 nurses are approved by the Board of Medical Examiners as mobile intensive care nurses, authorizing them to give orders over the radio to EMT-intermediates and EMT-paramedics in the field.

Another significant achievement in the area of training is the establishment of residency programs in emergency medicine at Bowman Gray School of Medicine, Charlotte Memorial Hospital, and East Carolina School of Medicine. Together they have 36 emergency medicine resident positions which serve as an important source of physicians for staffing hospital emergency departments in the state. Emergency medicine was approved as a medical specialty in 1979 bringing new standards of training and expertise to physician staffing of the emergency department.

Hospitals and Medical Control

Hospital emergency services have also undergone a major transformation during the past decade. The emergency room has given way to the emergency department, symbolizing a much more organized and committed approach to treating the emergency patient on the part of an institution. This is further evidenced by the change in physician staffing patterns in the emergency department. In 1973 only 21 hospitals in North Carolina had 24-hour physician coverage in the emergency department. This has since risen to 76 or 63 percent of all hospitals in the state providing emergency services. An even greater number have coverage for one or two shifts each day and on the weekend. Tables 3 and 4 show the number of hospitals with 24-hour physician staffing in the ED by hospital bed size and number of ED visits annually. The Program on Access to Health Care played an influential role in this area by contributing over $3.2 million to 54 hospitals to assist them in establishing 24-hour coverage in the ED. The end result has been increased availability of medical care for the citizens of North Carolina, especially the critically ill and injured.

A less tangible, but equally important, change has been the increased involvement of the hospital and its medical staff in the overall emergency medical services system. An objective of the state EMS program has been to break down the barrier that has traditionally existed between the prehospital provider and the hospital ED to enhance the continuity of care from the scene to the emergency department. Advanced life support programs are considered an extension of the services of the hospital emergency department to the site of the accident or illness and, thus, regulations promulgated by the Board of Medical Examiners require that such programs be sponsored by a hospital, rather than by an individual ambulance provider. Currently 58 of the 120 hospitals offering emergency services serve as sponsor hospitals for advanced life support programs. Additionally, nine have been designed as resource hospitals with responsibilities for coordinating and standardizing ALS programs on a regional basis and for providing back-up physician support for field technicians associated with other sponsor hospitals. The strong medical orientation of these programs is further demonstrated by the requirement that each have a designated medical director.

Table 3

Hospitals with 24 Hour ED Physician Coverage by Bed Size — 1983

No. Beds in Hospital	No. of Hospitals	No. with 24 hr ED Coverage	Percent with 24 hr ED Coverage
0-50	13	0	0
51-100	30	9	30
101-150	25	19	76
151-200	17	15	88
201-250	3	3	100
251-300	7	6	86
301-350	6	6	100
351-400	3	2	67
401 & over	16	16	100
Totals	120	76	63

Table 4

Hospitals with 24 Hour ED Physician Coverage by Number of ED Visits — 1983

No. of ED Visits	No. of Hospitals	No. with 24 hr ED Coverage	Percent with 24 hr ED Coverage
1-1,000	3	1	33
1,001-3,000	7	0	—
3,001-5,000	9	1	11
5,001-10,000	27	8	30
10,001-15,000	22	15	68
15,001-20,000	16	15	94
20,001-30,000	19	19	100
30,001-40,000	9	9	100
40,001-50,000	5	5	100
50,001-60,000	2	2	100
60,001 and over	1	1	100
Totals	120	76	

One of the mandates given to the Department of Human Resources by the EMS legislation was the development of comprehensive emergency treatment centers. In this regard, the Office of Emergency Medical Services' attention has been largely directed to establishing a trauma system with designated centers for treating the most severe cases. Published studies show that reductions in morbidity and mortality can be achieved by concentrating the treatment and care of the severely traumatized patient in facilities specially equipped and staffed to handle them.[1, 2] To date, the Secretary has designated three statewide or Level I trauma centers — Duke University Medical Center, N.C. Baptist Hospital, and N.C. Memorial Hospital — and one regional or Level II trauma center, Pitt County Memorial Hospital. Such a designation recognizes the commitment of the institution to the treatment of the trauma victim and its willingness to meet criteria adopted by the State from that set forth by the American College of Surgeons. Efforts are ongoing to identify and designate regional trauma centers in other parts of the state.

In 1983 monies were appropriated by the General Assembly to establish a state poison control and information center. The Department of Human Resources entered into a contract with Duke University Medical Center to expand their existing services in this area to include a toll-free telephone line manned by trained poison information specialists 24 hours/day. A survey conducted by the Office of Emergency Medical Services in 1981 revealed 11 hospitals providing some type of poison information service to the general public, but with the exception of Duke, all served a smaller geographical area. Future activities will focus on tying the state center and the regional/local centers together into an effective network.

Finally, in the area of hospitals, all of those providing emergency services have been categorized according to their ability to treat emergent patients in eight critical care areas — trauma; burn; spinal cord; cardiac; behavioral; poisoning/drug; neonatal, perinatal and pediatric; and acute medical. Hospitals are categorized as a Level I, II, or III (I denotes greatest capability) in each area according to criteria set by the State through the State EMS Advisory Council. Those not meeting at least the Level III criteria for an area are not categorized.

Medical control is an important principle in the modern day emergency medical services system and one that is increasingly recognized as essential to the delivery of quality emergency medical care. In essence, medical control refers to the management and accountability for the medical care aspects of the EMS system — a direct recognition of the fact that EMS is medical in nature. It includes oversight of the training of the prehospital personnel, the development of treatment protocols for use by the prehospital technicians in rendering medical care in the field, and evaluation of the medical care provided by the system.[3]

Structurally, the concept of medical control begins with the medical director of the Office of Emergency Medical Services, who oversees the medical aspects of the state program, and continues throughout the entire EMS system. Each regional EMS council has a part-time medical director with responsibilities at the regional program level which include the development of region-wide treatment protocols for prehospital personnel, establishment of transfer agreements, categorization of hospital emergency services, and consultation on the medical content of training programs.

At the local level, medical control activities are much more operationally oriented. They involve giving orders to field technicians over the radio, evaluating the quality of prehospital emergency care, and assessing the capabilities of field technicians in addition to planning and administrative responsibilities similar to those of the regional medical director. A recent statewide survey showed that 151 ambulance providers claim to have a medical director. Unfortunately, their involvement in medical control activities is often very little. Advanced life support programs are required by regulation to have a system of medical control including a designated medical director. There is no such requirement for those functioning at the basic level, and those in ALS programs account for about one-half of the 151 who have a medical director. The lack of medical direction and medical control at the basic level is a shortcoming that needs to be addressed.

Transportation

A 1965 study of ambulance services in North Carolina reported that only 18 percent of the 905 ambulances in the state were straight ambulances while 54 percent were combination hearse and ambulance.[4] A subsequent survey by the Research Triangle Institute in 1972 found that only 311 of 776 ambulances could be considered suitable for EMS on the basis of vehicle age, type, equipment, etc.[5] Today the ambulance remains the single most visible symbol of emergency medical service, but the hearse and station wagon have given way to a vehicle that is better designed and equipped.

Surprisingly, the actual number of ambulances has not increased substantially relative to the extent of other improvements in EMS. In 1984, there are 1,164 ambulances permitted by the Office of Emergency Medical Services signifying compliance with minimum staffing and equipment standards set by the Medical Care Commission. Most are Category I ambulances, equipped and staffed to transport emergency cases, although legally they are authorized to carry non-emergency patients. State regulations were amended in 1983 to establish a Category II ambulance which is permitted solely to transport non-emergency cases between a residence and a medical facility or between two medical facilities. Because of the limitations of this type of vehicle, very few are in operation; however, their utilization is expected to increase in the years ahead.

Approximately 75 percent of the 1,164 vehicles meet the more exacting requirements of the Federal Ambulance Specification, which calls for 60 inches of headroom in the patient compartment versus a minimum state requirement of 52 inches. Recitation of the specific design and equipment requirements for ambulances would serve little useful purpose. The significant aspect of such changes is that ambulances are now designed with sufficient room for the patient and for two or more technicians to administer care while en route, as well as for the necessary rescue and medical equipment. Again, the patient and the delivery of emergency medical care are the focal points.

Ambulance coverage is provided to all parts of the state by the 514 ambulance services in the state, each of which operates 1 or more of the 1,164 permitted ambulances. Response time, the time from the receipt of the call for assistance to arrival at the scene, varies from community to community, but all counties report average response times within the state established minimums of 10 minutes in an urban area and 30 minutes in a rural area. Statewide, the average response time for emergency calls is 8.7 minutes. Of the 100 counties in the state, 66 report an average response time of 10 minutes or less; 32 of between 11 and 15 minutes; and only 2 over 15 (16 minutes). A recent survey conducted by the Office of Emergency Medical Services of all ambulance providers in the state showed that there was a total of 449,803 runs in 1983 (based on the fiscal year of the provider). Emergency runs comprised 55.9 percent of the runs and non-emergency 31.0 percent. Search and rescue, standby, and other miscellaneously classified calls made up the balance.

Tiered response systems have been established in some counties where first responder organizations have been formed for the purpose of further reducing the response time. First responders are organizations or agencies, most commonly fire departments, police departments, or non-transporting rescue squads, with personnel trained in basic emergency medical care who are dispatched to the scene to provide immediate care to the victim until the ambulance crew arrives. There are 130 such organizations in North Carolina functioning in 26 counties.

The MAST (Military Assistance to Safety and Traffic) Program operated by the 57th Medical Detachment out of Fort Bragg provides the state's only helicopter emergency medical evacuation service. Several hospitals have stated an interest in establishing a hospital-based helicopter program. Given the recent interest, the entire area of emergency air evacuation is being studied by the Department of Human Resources to ascertain the approach that might best serve the citizens of North Carolina.

Communications

Communications is often said to be the thread that ties the various elements of the EMS system together. If this is the case, there was certainly very little holding North Carolina's EMS system together prior to the early 1970s. Public access to prehospital emergency medical care was difficult and complicated by the variety of telephone numbers to be called within a county to request an ambulance. Dispatch was often slow and uncoordinated. Even if the ambulance and the hospital both had two-way radios, they were more likely than not to be on different frequencies so that the ambulance personnel and hospital ED staff could not communicate with each other. Often ambulances within the same service had different radio frequencies and coordination with other public safety agencies was practically nonexistent.

A simplified means of access to prehospital emergency care continues to be a goal of the state EMS program. Only 10 counties have implemented 911 systems countywide for use in obtaining police, fire, and emergency medical assistance. This remains the ultimate target, but progress is slow for many reasons including turf and political squabbles among local public safety agencies, costs, and the multiplicity of phone companies across the state. Another 54 counties have at least a single seven-digit number countywide for calling for an ambulance, the minimum deemed acceptable by the Office of Emergency Medical Services. While considerable progress has been made, multiple telephone numbers, which can cause unnecessary confusion and delay, still exist in 36 counties. Coordinated dispatch through a single central point is possible in 63 counties.

Ambulance and ambulance to hospital communications have improved significantly, particularly in terms of coordination and standardization among local jurisdictions. All of the 120 hospitals providing 24-hour emergency service have two-way radios and the capability to transmit and receive on the VHF (very high frequency) frequencies of 155.280 MHz and 155.340 MHz. Among the State's ambulances, 97 percent have operational two-way radios equipped to operate on the standard VHF frequencies, enabling the field technicians to talk directly with a physician or nurse in the hospital emergency department.

Having achieved statewide standardization for the most part, the VHF spectrum serves as the basic communications system for EMS, although the limited frequencies available pose some crowding problems. In 1973 the Federal Communications Commission allocated 10 frequency pairs on the UHF (ultra high frequency) spectrum for medical communications and authorized their use for the transmission of biomedical telemetry, an essential part of an EMT-paramedic service. Cost, as well as a lack of an immediate need, caused the Office of Emergency Medical Services to decide to implement UHF EMS communications systems on a county by county basis, rather than attempting to move immediately statewide. Priority has been given to those counties that have an EMT-paramedic program or are planning to initiate one and, thus, have a need for biomedical telemetry. Presently, 30 counties have complete UHF EMS communications systems. These are supported by a network of 14 areawide radio repeater sites operated and maintained by the Office of Emergency Medical Services which facilitate inter-county and regional EMS communications.

The Future

The general public has come to appreciate and recognize the value of a good emergency medical services system. Consequently, their expectations are much greater today than they were 10 years ago — and they should be. Paramount among the issues facing EMS in the future is the quality of the medical care rendered to the critically ill and injured. Efforts so far have focused on system development, yet the establishment of a system brings with it the responsibility to maintain and improve upon the level and quality of the service. Attention must be directed to building quality assurance procedures and protocols into the system at various points, just as hospitals and their medical staffs have had to do. Additionally, research in emergency medicine and evaluation of the delivery system will play a greater role in tomorrow's EMS system than it has in the past. The EMS system will have to maintain its flexibility to adjust to new and more effective treatment modalities and service delivery methods and incorporate them into ongoing operations.

Although there have been many improvements in the delivery of emergency medical care, North Carolina's EMS system is far from complete. However, a solid foundation has been laid and the basic framework established for the continued development of the system.

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SCIENTIFIC ARTICLE

A Philosophy for the Care of Trauma Patients With Multiple Musculoskeletal Injuries

Laurence E. Dahners, M.D.

• *A primer on the care of the patient with musculoskeletal injuries, from the acute period to rehabilitation.*

Introduction

IN this day of high speed motor vehicle accidents, multiple injuries in a single patient are a frequent problem. Largely because of the efforts of the American College of Surgeons Advanced Trauma and Life Support Courses (ATLS) our ability to transport, resuscitate and stabilize these patients has improved and more patients are surviving the acute injury to require more definitive treatment. This means that the physician is sometimes called upon to address the patient with multiple extremity injuries and must decide when, how and in what order to treat these injuries.

The purpose of this paper is to discuss where, in the general priority of things, the locomotor injuries should be addressed and the order in which they should be treated. In addition, there is some discussion of how the treatment of a particular fracture, in the setting of multiple fractures, differs from the care of the single fracture alone.

Where Musculoskeletal Injuries Fall in the General Scheme of Trauma Care

It is useful to divide the care of the polytrauma patient into five stages: acute, primary, secondary, tertiary and rehabilitative. In the first or acute stage immediate life threatening injuries such as pneumothorax, massive bleeding or intracranial hemorrhage should be treated and musculoskeletal injuries usually can be ignored. In the primary phase visceral injuries such as bowel rupture and limb threatening injuries such as vascular disruptions, compartment syndromes, open fractures and open joints are treated. In addition, it is probably important to operatively stabilize major long bone fractures during this period if feasible. During the secondary period attention is turned to sustaining the vital organs through a post-traumatic illness characterized by catabolism and pulmonary dysfunction. In the tertiary period complex joint fractures are reduced and fixed, ligaments are repaired, and wounds are covered. Finally, in the rehabilitative period reconstructive operations such as bone grafts and arthroplastic procedures are carried out.

Acute Period (Lifesaving)

The acute period is a time of resuscitation from life-threatening injuries to the heart, lungs or central nervous system. The management of the patient during the acute period is well addressed by the ATLS course and physicians involved in the care of trauma patients should strongly consider taking the course.

During this period it may be necessary to address one orthopedic injury and that is the unstable pelvic fracture. These fractures involve the major ring of the pelvis and are displaced more than one centimeter. They are often responsible for life-threatening hemorrhage and, while the first line of defense is fluid replacement and tamponade with MAST trousers, sometimes early external fixation may be life saving. Placing three to six percutaneous pins in each iliac wing and connecting them with an external frame stabilizes the pelvis, thus preventing the constant disturbance of clots formed on the rapidly bleeding cancellous bone bed. In general this form of stabilization provides more reliable control of hemorrhage (>90% in one series) than radiographic arterial embolization (10%).

The acute period should last only one to two hours and there are only two other orthopedic injuries which should be considered during this period. These are dislocations of the knee and subtalar joint, which often obstruct the adjacent vessels (the popliteal and posterior tibial, respectively). Often they are very easily reduced by increasing the deformity, applying hand traction, and easing the limb back into a normal position. Fifteen seconds spent thus may save a limb without undue risk to life. Of course the first priority should be oxygenation and circulation to the vital organs and repeated attempts at reduction cannot be justified.

Primary Period (Limbsaving)

The primary period is that first, "golden," twelve hours after injury while the patient is in relatively good condition. Post-traumatic respiratory distress has not set in as yet, the wounds have not become soupy and secondarily infected and the patient will probably tolerate surgery better than he will anytime in the next several days or weeks. It may be a serious mistake to put off a procedure "until he's in a little better shape," especially when some of those procedures may shorten the course of his post traumatic illness.

From the Trauma Section, Department of Surgery, University of North Carolina, Chapel Hill 27514.

During the primary care period transfer to a tertiary care center should be considered if the multiplicity of injuries warrants it, the distance is not too great, and the patient seems stable enough to tolerate the transfer. The problems which must be addressed during the primary period are those which will present a significant threat to life or limb if not treated within six to twelve hours. Included are such non-locomotor injuries as peritoneal soiling from rupture of the hollow organs.

In the care of the locomotor system the first priority is to restore perfusion. Vascular repair should be carried out and limbs displaying signs of a compartment syndrome should have fasciotomy. A dislocated knee or subtalar joint must be reduced by now and in addition dislocations of the hip (which compromise the blood supply to the femoral head) should be reduced. If perfusion of muscular tissue is not restored within six hours the success rate falls off dramatically. Time should not be lost in the radiology suite obtaining definitive angiography; rather a single shot arteriogram of the injured area should be obtained in the operating room (this is almost always adequate).

The next priority is the debridement and irrigation of open fractures and in the multiply injured patient strong consideration should be given to operative stabilization of open fractures of the femur and tibia. This operative stabilization is usually achieved by external fixation, but occasionally internal fixation is appropriate. While external fixation is without a doubt the safest means, internal fixation should be considered for fractures which are relatively clean, for those in which the approach for internal fixation has already been made by the traumatic injury, and for displaced articular fractures.

Major trauma centers have recently produced evidence that rigid operative stabilization of major long bone fractures (especially the femur) during the primary period decreases the severity of the post traumatic respiratory distress syndrome. Therefore, strong consideration should be given to intramedullary nailing of femur fractures, by closed techniques if possible, but by open technique if necessary. Many would advocate nailing of grade one open (small, clean, open wound produced by the bone puncturing the skin from the inside out) femur fractures as well. Some would even advocate extending the indications for intramedullary nailing, in the multiple trauma patient, to include those outside the middle third and those with comminution. Another solution is a simple, single bar, lateral, external fixator (such as the Wagner leg lengthening device), which connects pins in the greater trochanter to pins in the supracondylar region. This acts as a "mobile traction unit" allowing early mobilization of the patient out of the supine position for better pulmonary toilet.

Secondary Period (Fine Tuning of the Vital Organs)

During this period the major objective is to sustain the patient through a frequently severe post-traumatic illness, characterized by respiratory insufficiency and a catabolic state. Ventilatory support and alimentation (by feeding tube if possible or by venous routes if necessary) are the keystones of treatment. Providing optimal care (such as early alimentation) is very important to the effort of keeping this period as short as possible (preferably under one week) because many of the complex surgical procedures of the tertiary period are very difficult two weeks after injury.

During this period further insult to the system, in the form of surgical procedures, should be avoided if possible. It is of great importance to eliminate septic foci which will prolong or increase the illness. Transcutaneous lines should be changed and wound dressings closely observed. Infected wounds must be drained and debrided, and occasionally something as drastic as an amputation may be necessary to eliminate a source of sepsis.

Tertiary Period (Fine Tuning of the Locomotor System)

When the patient's respiratory status has improved and he has become anabolic, further surgical treatment of the locomotor system is appropriate. Ligamentous repairs, as well as reduction and fixation of upper extremity fractures and closed articular fractures should be undertaken during this time. Wounds are closed or skin grafted and flaps may be swung during this period if necessary. Spine fractures are usually stabilized by operative means during the tertiary period, though very unstable fractures with neurologic sparing may need to be done during the primary period to allow mobilization of the patient (for pulmonary toilet) without risk of further neurologic injury.

When the illness of the secondary period lasts more than one to two weeks the physician is often faced with a difficult choice. He may operate while a good reduction or repair is still possible (within one to two weeks of injury) but incur risks of anesthetic complication and wound infection. On the other hand, he may wait to operate until the risk is less but will be forced to accept less than optimal locomotor results in the long run.

Rehabilitative Period

The rehabilitative period falls after all surgical repairs are completed. It is a time during which the patient is mobilized by physical therapy, the fractures heal and the patient is restored to the best obtainable locomotor status. This period may last for the remainder of the patient's life and through many reconstructive procedures.

Bone grafts to stimulate healing of delayed or nonunions of fractures are certainly appropriate. Malunions of fractures not treated satisfactorily because of intervening factors may need to be taken down and reduced. Ligament reconstructions for unstable joints and muscle transfers for motor deficits may be needed. Joint arthroplasty or arthrodesis may be necessary for joints which could not be adequately repaired during the tertiary period.

Operative Versus Nonoperative Treatment in the Multiply Injured Patient

There is accumulating evidence in favor of taking a more aggressive operative approach to multiple fractures. This has been shown to be important in the treatment of femoral fractures because of the improved pulmonary toilet that early mobilization allows. Some trauma surgeons go so far as to liken traction to crucifixion of the multiply injured patient. They feel that the supine position results in ventilation/perfusion mismatch, pneumonia, deep venous thrombosis, pulmonary embolism and decubiti.

Multiple fractures often respond poorly to nonoperative treatment because optimal conservative treatment of one fracture compromises the treatment of other fractures. This is especially true of multiple fractures in the same limb where the optimal position for reduction of one fracture may prevent reduction of another. Ipsilateral femur and tibia fractures have a high incidence of malunion and nonunion unless treated operatively. Gravity is often an important factor in the reduction of a humerus fracture and in the supine patient with a femur in traction it may be very difficult to maintain adequate humeral fracture reduction. It may be wise to internally fix the femur so that the patient may be maintained in an upright position for nonoperative treatment of the humerus.

Many of the fractures in the multiple trauma victim will be open because of the high energy of the accident. For many physicians this raises the dilemma of how to stabilize the fracture for the best care of the soft tissues and mobilization of the patient. An external fixator is the safest means for this, providing rigid immobilization of the fracture, without extensive surgical dissection for device application as with internal plates. In addition to providing better immobilization of the fracture (and thus protection of wounded tissues) without immobilization of the adjacent joints, it also allows better wound care (access) than a cast. In some cases an extensive wound allows application of internal fixation devices without further dissection (and thus injury to the blood supply) and in this instance internal fixation is probably justified. Suboptimal internal fixation devices (short plates or circlage wires alone) are not justified as they will usually fail, leaving you with the worst of both worlds (an unstable fracture with a foreign body).

Open, displaced, articular fractures should usually be treated with internal fixation as it provides the only means for maintenance of a perfect reduction. A windowed cast is seldom capable of maintaining reduction. It serves little purpose to ensure post-traumatic arthrosis secondary to malreduction of articular surfaces because of a fear of post-infectious arthrosis. There is experimental as well as clinical evidence now that fractures immobilized by internal fixation do as well in the face of infectious organisms as those treated without implants. Internally fixed fractures have a lower incidence of malreduction, and if they become infected, the infection does not seem to be as severe as in fractures healing with large quantities of callus (as in a cast).

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ibuprofen

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Contraindications: Anaphylactoid reactions have occurred in individuals hypersensitive to *Motrin* Tablets or with the syndrome of nasal polyps, angioedema and bronchospastic reactivity to aspirin, iodides, or other nonsteroidal anti-inflammatory agents

Warnings: Peptic ulceration and GI bleeding, sometimes severe, have been reported Ulceration, perforation and bleeding may end fatally An association has not been established Use *Motrin* Tablets under close supervision in patients with a history of upper gastrointestinal tract disease after consulting ADVERSE REACTIONS In patients with active peptic ulcer and active rheumatoid arthritis, try nonulcerogenic drugs, such as gold If *Motrin* Tablets are used, observe the patient closely for signs of ulcer perforation or GI bleeding

Chronic studies in rats and monkeys have shown mild renal toxicity with papillary edema and necrosis Renal papillary necrosis has rarely been shown in humans treated with *Motrin* Tablets

Precautions: Blurred and/or diminished vision, scotomata, and/or changes in color vision have been reported If these develop, discontinue *Motrin* Tablets and the patient should have an ophthalmologic examination, including central visual fields and color vision testing

Fluid retention and edema have been associated with *Motrin* Tablets, use with caution in patients with a history of cardiac decompensation or hypertension In patients with renal impairment, reduced dosage may be necessary Prospective studies of *Motrin* Tablets safety in patients with chronic renal failure have not been done

Motrin Tablets can inhibit **platelet aggregation** and prolong bleeding time Use with caution in persons with intrinsic coagulation defects and on anticoagulant therapy

Patients should report signs or symptoms of **gastrointestinal ulceration** or bleeding, skin rash, weight gain, or edema

Patients on prolonged **corticosteroid therapy** should have therapy tapered slowly when *Motrin* Tablets are added

The antipyretic, anti-inflammatory activity of *Motrin* Tablets may mask inflammation and fever

As with other nonsteroidal anti-inflammatory drugs, borderline elevations of liver tests may occur in up to 15% of patients These abnormalities may progress, may remain essentially unchanged, or may be transient with continued therapy Meaningful elevations of SGPT or SGOT (AST) occurred in controlled clinical trials in less than 1% of patients Severe hepatic reactions, including jaundice and cases of fatal hepatitis, have been reported with ibuprofen as with other nonsteroidal anti-inflammatory drugs. If liver disease develops or if systemic manifestations occur (e.g eosinophilia, rash, etc), *Motrin* should be discontinued

Drug interactions. *Aspirin*: used concomitantly may decrease *Motrin* blood levels

Coumarin: bleeding has been reported in patients taking *Motrin* and coumarin

Pregnancy and nursing mothers: *Motrin* should not be taken during pregnancy or by nursing mothers

Adverse Reactions: The most frequent type of adverse reaction occurring with *Motrin* is gastrointestinal of which one or more occurred in 4% to 16% of the patients

Incidence Greater than 1% (but less than 3%)—Probable Causal Relationship

Gastrointestinal: Nausea,* epigastric pain,* heartburn,* diarrhea, abdominal distress, nausea and vomiting, indigestion, constipation, abdominal cramps or pain, fullness of GI tract (bloating and flatulence); **Central Nervous System**: Dizziness,* headache, nervousness, **Dermatologic**: Rash* (including maculopapular type), pruritus, **Special Senses**: Tinnitus, **Metabolic/Endocrine**: Decreased appetite, **Cardiovascular**: Edema, fluid retention (generally responds promptly to drug discontinuation, see PRECAUTIONS)

Incidence less than 1%—Probable Causal Relationship**

Gastrointestinal: Gastric or duodenal ulcer with bleeding and/or perforation, gastrointestinal hemorrhage, melena, gastritis, hepatitis, jaundice, abnormal liver function tests, **Central Nervous System**: Depression, insomnia, confusion, emotional lability, somnolence, aseptic meningitis with fever and coma **Dermatologic**: Vesiculobullous eruptions, urticaria, erythema multiforme, Stevens-Johnson syndrome, alopecia, **Special Senses**: Hearing loss, amblyopia (blurred and/or diminished vision, scotomata, and/or changes in color vision) (see PRECAUTIONS), **Hematologic**: Neutropenia, agranulocytosis, aplastic anemia, hemolytic anemia (sometimes Coombs positive), thrombocytopenia with or without purpura, eosinophilia, decreases in hemoglobin and hematocrit, **Cardiovascular**: Congestive heart failure in patients with marginal cardiac function, elevated blood pressure, palpitations, **Allergic**: Syndrome of abdominal pain, fever, chills, nausea and vomiting, anaphylaxis, bronchospasm (see CONTRAINDICATIONS), **Renal**: Acute renal failure in patients with pre-existing significantly impaired renal function, decreased creatinine clearance, polyuria, azotemia, cystitis, hematuria, **Miscellaneous**: Dry eyes and mouth, gingival ulcer, rhinitis

Incidence less than 1%—Causal Relationship Unknown**

Gastrointestinal: Pancreatitis, **Central Nervous System**: Paresthesias, hallucinations, dream abnormalities, pseudotumor cerebri, **Dermatologic**: Toxic epidermal necrolysis, photoallergic skin reactions, **Special Senses**: Conjunctivitis, diplopia, optic neuritis, **Hematologic**: Bleeding episodes (e.g. epistaxis, menorrhagia), **Metabolic/Endocrine**: Gynecomastia, hypoglycemic reaction, **Cardiovascular**: Arrhythmias (sinus tachycardia, sinus bradycardia); **Allergic**: Serum sickness, lupus erythematosus syndrome, Henoch-Schonlein vasculitis, **Renal**: Renal papillary necrosis

*Reactions occurring in 3% to 9% of patients treated with *Motrin* (Those reactions occurring in less than 3% of the patients are unmarked)

**Reactions are classified under "*Probable Causal Relationship (PCR)*" if there has been one positive rechallenge or if three or more cases occur which might be causally related Reactions are classified under "*Causal Relationship Unknown*" if seven or more events have been reported but the criteria for PCR have not been met

Overdosage: In cases of acute overdosage, the stomach should be emptied The drug is acidic and excreted in the urine so alkaline diuresis may be beneficial.

Dosage and Administration: Rheumatoid arthritis and osteoarthritis Suggested dosage is 300, 400, or 600 mg t i d or q i d Do not exceed 2400 mg per day Mild to moderate pain 400 mg every 4 to 6 hours as necessary

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SCIENTIFIC ARTICLE

New Principles of Resuscitation for Brain and Spinal Injury

Michael J. Rosner, M.D., Zev Elias, M.D. and Irene Coley, P.A.-C.

- *Current do's and don't's in the early care of patients whose injuries affect the brain and/or spinal cord.*

THE resuscitation and care of the brain injured patient begins with a clear statement of the neurologic condition of that patient. This is important for purposes of communication with referral centers as well as to clarify issues for the treating physician. Such terms as "stuporous," "obtunded," and "altered mental status" have little intrinsic meaning and vary widely in the manner in which they are used; in recent years they have been replaced by the Glasgow Coma Scale (GCS), table 1. Particularly for the purposes of communication, the Glascow Coma Scale has shown itself to be extremely objective and easily learned, and provides a uniform terminology for communication with other physicians.

The core of the Glascow Coma Scale is its treatment of the neurologic exam as a stimulus response arrangement with either voice or painful stimuli producing a verbal or motor response. Thus, patients either open their eyes spontaneously, or to voice, or to pain, or not at all, and such terms as stuporous and lethargic are never required. Similar scales are used for assessing verbal and motor responses. The Glascow scale is also easily adapted to intensive care or recovery room flow sheets.

Depression in the level of consciousness, or lack of eye opening to voice or pain, implies a very few reasonably specific alterations in either the anatomic or physiologic status of the patient. For consciousness to be intact, the reticular activating system in the deep medial structures of the brain stem must be intact. Small lesions in this system and somewhat higher up in the diencephalon are able to produce impairment in the level of consciousness. Depression in the level of consciousness may also be brought about when very large areas of the hemisphere are affected by a lesion, even though the brainstem may be intact. The implication is that lesions that affect only relatively small areas of the hemisphere do not produce significant depression in the level of consciousness. This is typical of the vast majority of hemispheric infarcts or strokes, small intracerebral hematomas, and many small traumatic contusions. Lesions that affect the hemispheres diffusely, such as anoxia, ischemia, and metabolic poisons such as barbiturates, are capable of depressing the level of consciousness without first affecting the brainstem. Many penetrating cerebral wounds, such as stab wounds of the cranium or low velocity bullet wounds such as inflicted by a .22 caliber short pistol, may actually affect only a small volume of hemispheric tissue and these patients may well present to the emergency room spontaneously opening their eyes, speaking, and following commands.

TABLE 1
Glasgow Coma Scale

Eye Opening	
Spontaneous	4
To verbal command	3
To pain	2
None	1
Vocal Response	
Oriented/conversant	5
Disoriented	4
Inappropriate words	3
Incomprehensible sounds	2
None	1
Motor Response	
Obeys commands	6
Localizes pain	5
Flexion-withdrawal	4
Flexion-abnormal	3
Extension	2
None	1

The pupillary light response and extraocular motility provide assessments of brainstem function in addition to level of consciousness and these are worth a very brief review. Pupillary constriction is a function of the intact 3rd nerve which has its nucleus ipsilaterally near the top of the brainstem (mesencephalon). A light stimulus applied to the eye causes reflex constriction of the pupil by more or less direct connections from the lateral geniculate body to the 3rd nerve nuclei. The 3rd nerve and its nuclei are responsible for medial, superior and inferior movement of the eye, as well as pupillary constriction. The 6th nerve moves the eye laterally via the lateral rectus muscle and has its nucleus on the ipsilateral side of the pons, which is just about an inch and a half below the 3rd nerve nucleus. The 3rd and 6th nerve nuclei are connected by means of the medial

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From the Trauma Service, Section of Neurosurgery, Department of Surgery, University of North Carolina — North Carolina Memorial Hospital Statewide Trauma Center, Chapel Hill 27514.

longitudinal fasciculus (MLF), which also connects to the corresponding contralateral structures. Thus, when gaze is directed to the left, the left lateral rectus contracts, the right medial rectus contracts and the antagonist muscles relax, all coordinated by the MLF. In patients with severe abnormalities in the level of consciousness, passive movement of the head from side to side will leave the eyes moving together as if they were staring at a fixed point in space. This is known as the oculocephalic reflex or the "dolls eyes" maneuver. Thus, intact "dolls eyes" to examination in the patient with a depressed level of consciousness implies that the segment of brainstem from the pons to the mesencephalon is more or less intact.

Decortication and decerebration are both terms which have been replaced on the Glasgow coma scale by "abnormal flexion" and "abnormal extension." A more general term for these abnormal movements is "posturing." Abnormal flexion implies loss of inhibitory input upon the red nucleus and, therefore, unimpeded activity of the rubrospinal tract (increasing flexor tone). "Abnormal extension" is similar in that it occurs when inhibition from supranuclear structures upon the vestibular nuclei in the pons is lost and the vestibulospinal tract is unhampered; extensor tone and movements are facilitated. Any lesion capable of impairing the supranuclear inhibition of these structures is thus capable of producing decortication or decerebration and the presence of these movements is specific for where a lesion is *not* as opposed to where it specifically *is*. Very large hemispheric lesions such as anoxia, or large ischemic infarcts, are able to produce this loss of inhibition just as precisely placed, smaller lesions, limited to inhibitory tracts, may produce such behaviors.

When the pupillary light reflex and extraocular motility are intact in a patient exhibiting posturing-type movements, then the neurologic condition is usually metabolic in origin and not related to a mass lesion. This is because the areas that subserve these abnormal motor movements are very closely related to those that subserve the pupillary and extraocular motor function. If the latter are intact, then the implication is that a *mass* lesion is not causing the dysfunction.[6]

An emerging concept in the care of brain injured persons is the cerebral perfusion pressure (CPP). This is defined as the difference between the systemic arterial blood pressure and the intracranial pressure. Normally, the cerebral perfusion pressure is between 80 and 100 mm Hg. It can be adversely affected by increases in the intracranial pressure or decreases in the systemic arterial pressure. The immediate implication is that if a patient with an intracranial mass lesion (high ICP) presents in shock (low SABP), then his cerebral perfusion pressure is probably very low indeed. Cerebral blood flow, even in the face of autoregulation, is dependent upon CPP and falls off rapidly when cerebral perfusion pressure drops below 60 mm Hg; this can cause ischemic damage superimposed on the mechanical effects of the injury (figure 1).

Hypoxemia is a very powerful cerebral vasodilator, as is hypercarbia. Therefore, the effects of hypoxemia, in addition to potential hypoxic damage, include increasing the intracranial pressure because of the increase in cerebral blood volume which occurs as the result of vasodilatation. Hypercarbia acts in a similar manner. Both can lead to severe impairment of the CPP.

By applying these simple physiologic principles, it is immediately apparent that shock in the face of a cerebral mass lesion in a patient who is hypoxic and potentially retaining CO_2 produces an absolutely devastating scenario in which the cerebral perfusion pressure is successively lowered by each of these factors. It is no surprise that many fatal cerebral injuries are accompanied by pathologic evidence of ischemic infarction and anoxic cell change.

Any patient suspected of having a brain injury should immediately undergo fluid resuscitation in an effort to normalize his systemic arterial blood pressure. Immediate knowledge of the intracranial pressure in the emergency room is usually not available, but treating the patient *as if* his intracranial pressure is elevated in the face of a low blood pressure is a very practical approach. Similarly, the use of intubation and mechanical ventilation in any patient who even appears to have marginal respirations or thoracic injury would help to avoid or ameliorate the effects of hypoxemia and hypercarbia.

It is obvious that one does not intubate patients who have had only transient loss of consciousness, and this form of therapy as a routine for brain injury should be reserved for

1. patients who have obvious chest injuries such that hypoxemia is likely to occur;
2. patients whose motor response to painful stimulus is no better than normal flexion or withdrawal;
3. patients who are unable to follow commands.

Using the latter criterion alone, for every 100 patients *unable to follow commands* when admitted to the emergency room, thirty to forty will die or remain in a persistent vegetative state. Fifty to sixty will make a good to moderately good recovery, and approximately 10% will be severely disabled.[2, 5] Only a few patients will be unable to follow commands because of the temporary effects of drugs, alcohol, or less severe transient injuries. So this patient, who is unable to obey commands, must be viewed as having suffered a major brain injury *until proven* otherwise.

The key to optimizing recovery from brain injury is early and immediate removal of a mass lesion in those patients harboring one (40% of those who cannot follow commands when first admitted to the emergency room). The remainder of the treatment of these patients is avoiding a secondary insult such as anemia, hypoxemia, and hypotension. It follows that these maneuvers and a definitive neurosurgical evaluation must occur very quickly to optimize results. Currently the most effective and fastest technique for the evaluation of the presence of a mass lesion is the CT scan. If an obviously, and severely, brain injured patient arrives at an emergency room without CT scan facilities, arrangements ought to be made immediately for his transfer after restoration of blood volume and oxygenation. If these facilities are locally available, they should be used.

Mannitol is an osmotically active agent which decreases the viscosity of the blood, improves red cell deformability, and thereby enhances cerebral blood flow and oxygen delivery. Because blood flow and oxygen delivery have been improved by this agent, vasoconstriction is able to occur

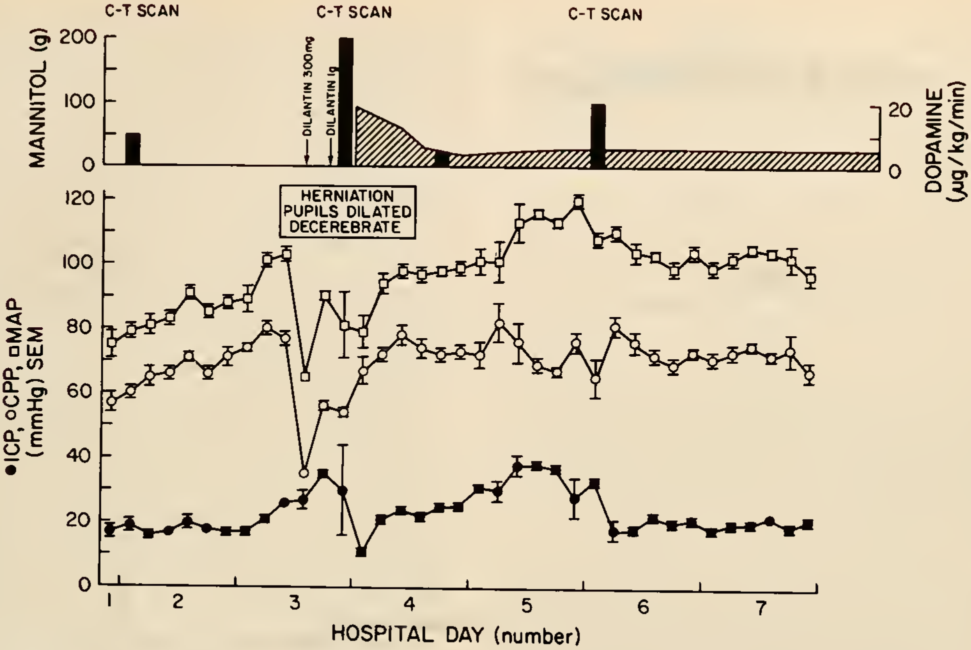

Figure 1. *This graph depicts the systemic arterial pressure (MAP), cerebral perfusion pressure (CPP), and intracranial pressure (ICP) over the first week in a patient who has just had an acute right subdural hematoma removed. For the first 48 hours, the ICP generally remained low (<20 mm Hg) but was accompanied by increasing systemic pressure. The patient remained neurologically stable, which involved opening his eyes to command, localizing a stimulus on the right and demonstrating a withdrawal response on the left. By the third day, he had a very slowly rising intracranial pressure and at approximately 4 a.m. he had a seizure. During the time of his seizure, his intracranial pressure went up substantially but because there was no perfusion pressure decrement he did not change neurologically. However, when 300 mg of Dilantin were given intravenously and followed by an additional 1000 mg, his systemic blood pressure dropped substantially, his perfusion pressure dropped to below 40, and his intracranial pressure rose very substantially. Both pupils became fixed and dilated and he became bilaterally decerebrate. Mannitol was given and a CT scan obtained which was basically unchanged from early after surgery. He was returned to the intensive care unit where he was placed on a dopamine drip in order to stabilize and elevate his systemic pressure to approximately 100 mm Hg and maintain his CPP at 70 or better. Only two additional doses of Mannitol were required and his ICP gradually stabilized. On the fifth day, an intracranial pressure spike occurred which was related to a drop in systemic pressure (not apparent on this graph). Mannitol was given and dopamine was continued. The patient did not change neurologically throughout this period and a CT scan was unchanged. The patient throughout improved and by the 7th day was opening his eyes to command, localizing painful stimuli with the right side and withdrawing on the left. Within the next few days, he was following verbal commands and using both sides purposefully. A mild hemiparesis was present at the time of his transfer. (Blood pressure, CPP, and ICP are plotted as the mean plus or minus SEM of 4 hourly observations; thus important transients which occurred with this patient are not necessarily obvious from this form of plot.)*

and cerebral blood volume is diminished. Mannitol may also have a dehydrating effect on the brain, though in recent years this has become controversial and, in fact, no direct evidence exists for mannitol being effective in removing edema or excess water from the brain.[6] However, it is extremely effective at stabilizing and at least temporarily reversing neurologic deterioration when it is due to a cerebral mass lesion.

If mannitol is to be used, it must be with the recognition that a massive diuresis will quickly occur and that a urinary catheter is necessary. After a single bottle of 20% mannitol (500 cc: 100 grams), the average adult will excrete between 1000 and 2000 ml urine. If this volume is not replaced, hypotension can be potentiated or precipitated, and the low perfusion pressure may *increase* ICP. Contrariwise, immediately after infusing a large bolus of mannitol extravascular water is drawn into the vascular space and immediate and effective volume expansion occurs. The blood pressure rises, tissue perfusion improves and ICP comes down (figure 2). However, this is transient because of the inevitable diuresis. Thus, mannitol is *not* contraindicated in the face of hypotension, but it *must* be accompanied by adequate fluid resuscitation.

Mannitol should be used immediately in any patient showing signs of progressive neurologic deficit, and in particular those with limb paresis and pupillary abnormalities. Given adequate fluid resuscitation and observation, it may be used as an agent to "buy time" while a patient is sent to CT scan. In days prior to CT scan, many neurosurgeons asked that mannitol not be given because it could

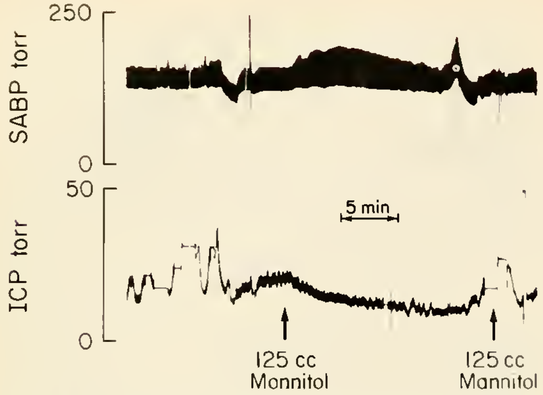

Figure 2. *This trace is from another brain injured individual and shows the effect of an infusion of a small dose of Mannitol upon both the ICP and blood pressure (SABP). Systemic pressure is elevated, intracranial pressure is reduced. This reflects both the improvement in perfusion pressure and the rheological effects of Mannitol which improve oxygen delivery to tissues.*

give a false sense of security when evaluating a newly arrived patient. However, with the advent of widespread CT availability, following patients "clinically" for deterioration is virtually useless. It is generally recommended that we identify those with a mass lesion *before* they dilate a pupil and herniate, and if mannitol can provide a time "buffer," then this is clearly worth any temporary uncertainty about specific neurologic findings or questions of progressive neurologic deficit. If in doubt, use mannitol, but replace the fluid lost!

The use of steroids in brain injury is modestly controversial. There have been two relatively recent prospective, double-blind studies using no steroids, low dose dexamethasone and high dose dexamethasone. Neither study succeeded in showing any improvement in either mortality or morbidity in the long or short term in either low or high dose steroid treated groups when compared with placebo (saline) treated controls.[1, 4] The complications of steroids also seem to be relatively minor, with only one study demonstrating an increase in pneumonitis in the high dose, steroid treated, brain injured group. A potential complication is the newly recognized tissue acidosis which seems to accompany injury. Hyperglycemia potentiates tissue acidosis and to the extent that steroids lead to hyperglycemia, they could be harmful. This has yet to be proven. While there seem to be relatively few detrimental effects of steroids, the issue still appears to evoke emotional responses, and the use of steroids should be left to the practice of the individual. Obviously, this writer is unconvinced of their utility.

The use of antacids, per NG tube, and cimetadine as prophylaxis against gastrointestinal hemorrhage has also been routine in the head injured patient. Often this use has been predicated on the presumed association of steroids and G.I. hemorrhage. It is quite obvious that gastrointestinal hemorrhage is a very frequent occurrence in those patients with severe brain injuries. However, this hemorrhage is equally frequent in those patients given steroids and those not receiving them;[1, 4] the entire issue has been reviewed by Conn and Blitzer.[3] However, gastrointestinal hemorrhage occurs extremely frequently in the severely brain injured. Much of this hemorrhage appears to be an erosive gastritis often induced by the presence of a hard nasogastric tube. While NG suction is almost always indicated in these patients, at least initially, the continued presence of a hard nasogastric tube should be minimized. If an NG tube is to be maintained in position, then it is recommended that antacids be used to titrate the pH of the stomach to 4 or above. The use of cimetadine prophylactically has been shown not to reduce the frequency of hemorrhage though there was some suggestion that the severity of hemorrhage may have been reduced, slightly, in a treated group.

The use of anticonvulsants is generally routine as prophylaxis for early seizures. The risk of seizure disorder in nonpenetrating brain injuries is generally less than 5-10% in both the long and short term. However, because the physiologic and practical consequences of an early seizure are so great, the use of prophylactic anticonvulsants is usually recommended. During an epileptic attack, the cerebral blood volume increases greatly, respiratory status is generally impaired and we have a situation where intracranial pressure may increase greatly in the face of decreased oxygen availability.

Concomitant hypertension usually maintains CPP and thus avoids most seizure related disasters. A previously unrecognized risk of seizure is hypotension, or hypotension relative to the blood pressure needed to maintain CPP, and may be induced by virtually any anticonvulsant (figure 1). Most brain injured patients can be withdrawn from anticonvulsants within the next 6-12 months.

"Standard" therapy for brain injured patients has evolved about *early* removal of a mass lesion and maintenance of an adequate blood supply to the brain.[2, 5] More recently, we have recognized that decrements in cerebral perfusion pressure may potentiate increased ICP and we have instituted protocols directed at treating the CPP.[8] Preliminary results are encouraging (figure 1).

Newer therapies directed at the accumulation of excess tissue acid, usually lactic acid, are also being evaluated at North Carolina Memorial Hospital.[9] Preliminary results are consistent with a marked reduction in the frequency of progressive, fatal intracranial hypertension. Regardless of the outcome of these clinical studies, they will only augment, not supplant, the essentials of resuscitation.

Spinal Cord Injury

Spinal cord injury has certain qualities in common with significant brain injury. Both tend to occur in the face of multiple systemic injury and are potentiated by anoxia and ischemia. Significant spinal cord injury accompanies brain injury in less than 5% of cases, but it has been standard teaching and remains so that the neurologic examination of a brain injured patient begins with a lateral cervical spine film. However, examination and resuscitation should not be delayed because of this requirement.

Spinal cord injuries can be classified according to four more or less discrete types. The first is a *transverse myelopathy* in which all modalities carried by the spinal cord are involved below the level of the lesion, i.e., posterior column function (vibration, position, touch), motor function, and pain and temperature function are lost below the given anatomic level. The *anterior cord syndrome* is a variant of this in which spinothalamic (pain and temperature) and corticospinal (motor) function are lost in the face of preserved posterior column function. Another variation is the *Brown-Sequard Syndrome* in which only half of the spinal cord is damaged, leading to ipsilateral loss of the posterior column and corticospinal functions and contralateral loss of pain and temperature. Any or all of these can be the result of a "garden" variety cervical or thoracic fracture, and they may (usually) be partially expressed and/or coexist.

The *central cord syndrome* has a somewhat different significance. Clinically, this presents as arm weakness which is greater than concomitant weakness in the lower extremities. This seems to relate to a pathologic lesion which is characterized by ischemic necrosis in the center of the spinal cord which extends centripetally with decreasing effects toward the periphery. The arm fibers in the corticospinal tracts are located more centrally than the leg fibers (which, teleologically, gives them a shorter distance to travel to the anterior horn cells) and thus are affected first and foremost by a lesion which is centrally located. Clinically, this lesion may be associated with varying degrees of sensory loss throughout the upper and lower extremities or even painful paresthesias in both upper extremities.

It is most often due to a hyperextension injury which does *not* produce an overt fracture dislocation of the spinal cord, but whose mechanism is dependent upon hyperextension, which transiently narrows the spinal canal by buckling of the ligamentum flavum and pinching the spinal cord between this ligament and the anterior aspect of the canal. It is particularly prominent in those of the fifth and sixth decades who suffer such hyperextension injuries. A classic presentation is that of a 60-year-old alcoholic who falls, strikes his forehead, and presents with a degree of quadriparesis (arms much weaker than legs) but no overt dislocation as judged by cervical spine x-ray. Often cervical spondylosis with narrowing of the spinal canal by osteophytes is prominent. This lesion is especially important since there is no associated spinal instability and it does not require skeletal traction for fixation. It is also easily misdiagnosed as due to malingering or hysteria. A firm cervical collar such as the Philadelphia cervical collar is usually sufficient. Soft Thomas collars are not optimally effective in immobilizing the cervical spine; they represent the best that is available at the roadside, but if significant cervical injury exists, they should be replaced by traction, halo fixation or a hard collar.

If plain cervical films reveal normal alignment, then voluntary flexion-extension x-rays can be obtained. Normal films tend to reassure the examiner that a major subluxation does not exist. However, in the presence of severe pain and muscle spasm one must be aware that enough splinting can occur to reduce and temporarily maintain reduction of a cervical fracture.

Given a patient with neurologic deficit related to the spine, it is best to assume instability and splint the patient. The same tenet applies to the neurologically intact patient who complains of severe neck pain. A firm collar, sand bags, bed rest should all be utilized until a more definitive evaluation can be completed.

The key to the systemic pathophysiology occurring in the face of spinal cord injury is recognition that the parasympathetic nervous system has the majority of its outflow via the vagus nerve which exists at the skull base. The sympathetic nervous system has its entire outflow via the thoracolumbar spinal cord which courses through the cervical cord. Thus, most of the vegative signs occurring in a spinal cord injured patient relate to varying degrees of sympathetic loss with unopposed parasympathetic activity.

The first major area of concern is recognition that most of the systemic vascular resistance is a function of the sympathetic nervous system. When this is lost, the systemic vascular resistance drops to extremely low levels (figure 3). With cervical cord injuries, this loss is almost total and typical values may be 400-500 dyne-sec/cm^5 (1100 is normal). Thus, even without hemorrhage and hypovolemia, the systemic arterial pressure in a cervical cord injury patient is usually somewhat less than normal. Systolic pressures in the range of 90 (mean pressures of about 60-70) are common and reflect a massive decrease in systemic vascular resistance and generalized vasodilatation.

Because the systemic resistance decreases massively and blood pressure decreases only slightly, it is obvious that cardiac output must actually increase. Many textbooks have suggested that cardiac output is low but in fact, when this parameter is actually measured, one finds that cardiac index is increased by 50-100%. Figure 3 shows multiple cardiovascular parameters measured as part of an ongoing study of the hemodynamics of quadriplegia at North Carolina Memorial Hospital.

With the loss of sympathetic innervation to the heart and its chronotropic effects, the unopposed action of the parasympathetic nervous system (vagus nerves) leads to varying degrees of bradycardia. At times, this bradycardia is intense and may reach levels of 40 beats/min or less. This bradycardia in the face of increased cardiac index results in greatly increased stroke volume index. These effects are generally well tolerated in the young, healthy patient; however, in middle-aged and elderly patients a syndrome, which effectively mimicks congestive heart failure, can be produced. This is simply because the demands upon the myocardium are greatly in excess of its ability to perform. Any underlying cardiac disease can substantially potentiate the bradycardia due to sympathectomy and unopposed parasympathetic activity and, at times, profound bradyarrhythmias — to the point of cardiac asystole — may occur. Traditional therapy for the bradyarrhythmias has been an anticholinergic, such as atropine, 1 mg IV p.r.n. This is very effective at restoration of the cardiac rate and rhythm and also improves systemic arterial pressure as well. However, it can do nothing for systemic vascular resistance and actually may potentiate problems when systemic resistance is very low and cardiac output has already reached a maximal level.

Administration of a sympathomimetic with both alpha and beta effect (to increase systemic resistance and heart rate simultaneously) appears logical and is, indeed, effective. Dopamine, often at lower than expected doses, tends to be very effective at improving systemic resistance, sys-

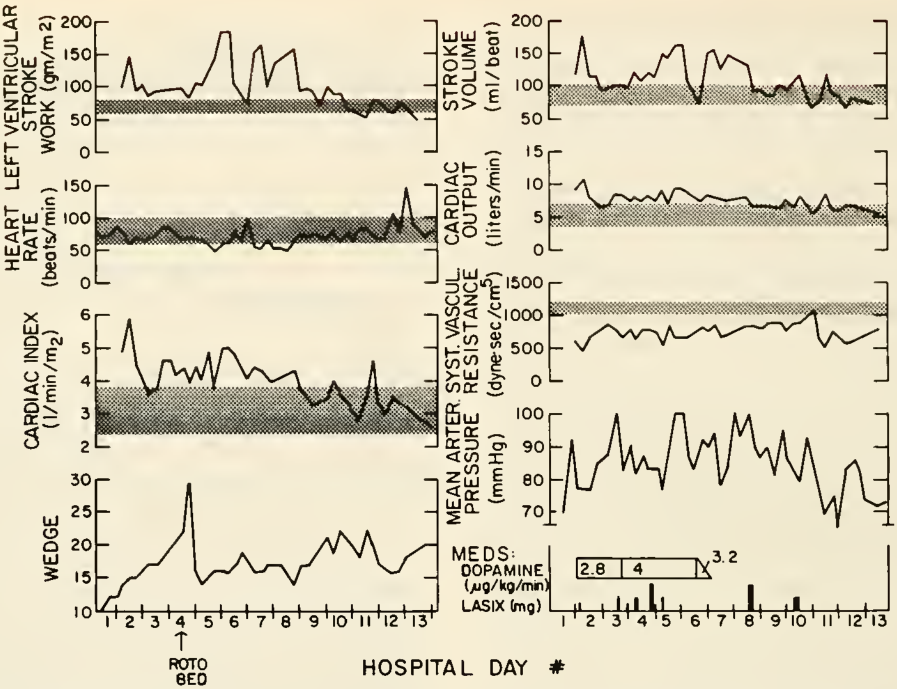

Figure 3. *This is a complex plot of the hemodynamic consequences of high quadriplegia. The important points are that systemic vascular resistance was extremely low in this patient and cardiac index was nearly twice normal. These changes gradually reversed with time but may have profound effects before they begin to resolve. This patient required the use of low dose dopamine to help stabilize his cardiovascular responses and actually showed a decrease in cardiac index with institution of a small amount of dopamine which helped increase his systemic vascular resistance. Because of rising pulmonary artery wedge pressures and hypoxemia and the development of a respiratory distress syndrome on day 4, diuretics were instituted and he was placed on an oscillating bed.*

temic pressure, and heart rate (figure 3). A pure alpha agonist does have some role when the heart rate is acceptable (especially likely in mid-thoracic spinal cord injuries. Here the primary problem is loss of peripheral vascular tone and low doses of phenylephrine, or a similar alpha agonist, are effective.)

Of equal importance is the respiratory system. All cervical spinal cord injuries of significant degree are associated with paralysis of the intercostal musculature. The intercostal musculature splints the chest such that the diaphragm can effectively expand the lung and provides respiratory excursion when more than the diaphragmatic motion is required. Loss of the intercostal function results in a tremendous decrease in both tidal volume and negative inspiratory force. Typical parameters for a mid to low cervical quadriplegic are negative inspiratory force of less than 25 cm H_2O and tidal volumes of 300 to 350 cc. Respiratory rate is unaffected and will often be higher than normal. Effective coughing and mobilization of secretions is extraordinarily difficult but is usually not an issue in the emergency room situation. However, within 24 hours it shall become one.

On admission, the pulmonary shunt fraction is usually 15-25%, which is in the range of severe impairment. Within 24-48 hours, this quotient will generally increase to 30-50%. This implies that the rapid development of hypoxemia will occur within the first day or two after a significant cervical spinal cord injury. Two courses of action are thus permitted. The first is prophylactic intubation and mechanical ventilatory support to maintain expansion of the alveoli and prevent successive and progressive alveolar collapse and atelectasis. The second is massive and aggressive pulmonary toilet instituted from the time of admission with concomitant and frequent (q4-q8h) bedside measurements of the vital capacity, tidal volume, and negative inspiratory force. A relatively new aspect of pulmonary toilet is the use of the oscillating bed (Kinetic Therapy Table or Roto Rest Bed). The rocking motion of the bed favorably affects ventilation-perfusion abnormalities and can markedly improve pulmonary shunt fraction (Qs/Qt) (figure 4). The improvement in Qs/Qt may be sufficient to avoid intubation in otherwise marginally compensated patients.

Intubation should be electively instituted (preferentially nasotracheal) given progressive deterioration in these values and/or the development of hypoxemia. It is preferable to institute intubation when these parameters are clearly worsening rather than wait for the development of a full-blown respiratory arrest, pneumonia, and/or diffuse atelectasis. Once established, these processes are very dif-

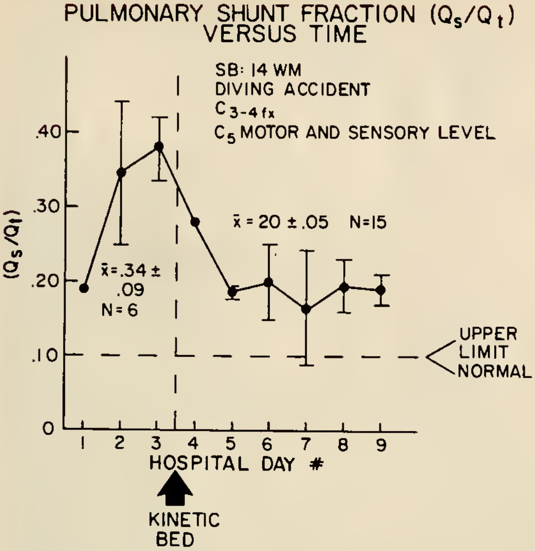

Figure 4. *This is the same patient as shown in figure 3. On admission, his pulmonary shunt fraction was somewhat less than 20%. This rapidly increased over the next 36 hours to nearly 40% with some values reaching 50%. He was placed on an oscillating bed and independent of any other therapeutic measures, his shunt fraction gradually and rapidly declined to the region of 20% and below. He remained stable at these lower levels thereafter.*

ficult to manage in the quadriplegic compared to the relative ease with which they are prevented. Because of the incipient pulmonary difficulties with high spinal cord injury, atropine, with its drying effect upon pulmonary secretions, is not recommended; while atropine may be lifesaving in the acute bradyarrhythmia, a sympathomimetic for such cardiac problems is doubly preferential.

Another major area affected by the autonomic nervous system in acute spinal cord injury is the gastrointestinal system. Loss of sympathetic tone and profound unopposed vagal activity results in noncoordinated activity of the gastrointestinal tract and the development of ileus. Since this is associated with continued activity of the gastrointestinal system (though uncoordinated), near normal bowel sounds are usually present but are misleading in the capacity of the bowel to accept enteral feeding. It may be 24-72 hours before bowel sounds disappear in the acute cervical spinal cord injury. However, if early feeding is undertaken, the ultimate development of ileus does not seem to be mitigated, but is worsened. In high cervical cord injury, a profound ileus with gastric and abdominal distention, which further increases upward pressure upon the diaphragm and decreases pulmonary reserve and function, is the rule rather than the exception. This author recommends withholding enteral feedings for 5-7 days. In lower cervical cord and thoracic injuries this period may be shortened, and in very low thoracic or lumbar lesions without significant intercostal paralysis ileus is much less of a problem and the consequences of its development, in terms of the pulmonary status, are much less severe.

Along with other pyramidal functions, the bladder and sphincters are often paralyzed. There are two primary approaches to acute bladder care. One is intermittent catheterization of the bladder on a q2-q4 hourly basis. This avoids semipermanent or permanent instrumentation of the bladder and helps reduce the risk of infection, but is predicated upon the availability of personnel with training to perform this procedure with the frequency required. Many paraplegics and quadriplegics will ultimately develop a spastic bladder which becomes automatic and empties reasonably well. However, if the urine volumes removed by intermittent catheterization are very large, as they may be if catheterization is not frequent enough, then a stretch injury to the bladder (which may be permanent) can result. If volumes removed by catheterization begin to exceed 350-400 cc, then the catheterization schedule must be adjusted. Again, this requires a mildly sophisticated and adequately staffed nursing group. The other less desirable but often more practical alternative is continuous catheterization. This may be medically indicated if problems with urinary output, congestive failure, sepsis, or the other problems associated with acute spinal cord injury or multiple trauma co-exist and make hourly urinary output desirable. This author recommends continuous Foley catheter from admission for at least 48-72 hours.

With significant spinal cord injury comes cutaneous anesthesia combined with paralysis. The central issue here is the potential development of decubitus ulcers, which significantly prolong hospitalization for these individuals. Frequent turning of the patient q1/2-q1 hour is mandatory. This improves the pulmonary shunt fraction because it helps improve ventilation-perfusion inequality in the lung which is the basis of this dysfunction. As noted, the introduction of oscillating beds, which continuously rotate the patient through a high degree of arc, has offered some assistance to nursing personnel. Skin care is improved and made easier, and at the same time the pulmonary status of the patient is significantly improved.

The use of skeletal traction, halo fixation, and early vs. late surgery for cervical fusion and/or mobilization remain rather controversial and are often dictated by regionally available neurosurgical and orthopaedic personnel. Most unstable cervical fractures, however, are treated with some degree of rigid immobilization while cervical spinal cord injuries characterized by bony stability (such as that which is typical of central cord syndrome) may often be treated with a firm cervical collar, such as the Philadelphia collar.

Specific Guidelines

It is worthwhile to remember a few basic principles, particularly when one is encountering a major brain or spinal cord injury in the middle of the night. One-half of the patients presenting with severe head injuries have significant alcohol levels in their blood. The presence of alcohol does not rule out a brain injury. It should not be used to explain a depressed or abnormal neurologic status nor the inability to follow commands for this will rarely be the case. Rather, the assumption should be that mechanical brain injury and/or mass lesion exist until proven otherwise. Most ''drunks'' can follow commands.

Begin the exam of a comatose patient with a lateral cervical spine x-ray. Do not delay the exam. It is not necessary to move the neck to ask a patient to wiggle his toes or squeeze the physician's fingers. In particular, do not delay fluid resuscitation and adequate ventilation of the patient for fear of a cervical spine injury.

As a mass lesion develops in a reasonably awake patient, agitation and combativeness often precede depression in the level of consciousness. This agitation and combativeness must not be confused with or explained away as intoxication; it will usually precede the development of a dilated pupil. By the time pupillary dilatation has occurred, the development of a mass lesion and intracranial decompensation has usually progressed quite far. The best time to salvage these individuals is before this progression occurs.

Given a patient who is demonstrating abnormal extension or abnormal flexion (decerebration or decortication) but who has intact pupillary and oculocephalic reflexes, this disturbance in consciousness is usually metabolic in origin. Profound hyperglycemia or hyopoglycemia, anoxic injury, and toxins will often be shown to be the basis for this condition.

Lastly, resuscitation of the brain injured patient requires precisely the same techniques as the abdominal or chest injury. The major difference is time. The brain is less tolerant, more demanding and less forgiving than most other organ systems. However, the rewards of dealing with these issues well are great.

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SCIENTIFIC ARTICLE

North Carolina Statewide Trauma Center Outreach Program

Joseph A. Moylan, M.D. and Joyce C. Pressley, M.P.H.

• *A description of a program to familiarize community hospitals with the state's Level I trauma centers.*

THE emphasis on emergency medical services in the past decade has resulted in significant improvements in medical care for the severely injured patient. Initial efforts focused on prehospital care and were successful in achieving higher standards for education and certification of personnel and for improvements in equipment and transportation. This was accomplished over a decade and a half largely through the efforts of the North Carolina Office of Emergency Medical Services. In more recent years, attention has focused on hospital care, particularly on the development of a trauma system to assure care appropriate to the level of injury regardless of geographic location of the patient. These efforts led to the development and designation of specialized care centers for the treatment of critically ill and injured patients. In 1982, three institutions were designated as Level I or Statewide Trauma Centers: Duke University Medical Center, North Carolina Memorial Hospital and North Carolina Baptist Hospital.

Due to the close geographic proximity of their respective trauma centers and the resulting overlapping patient catchment areas, Dr. Herbert Proctor of North Carolina Memorial Hospital and Dr. Joseph Moylan of Duke Medical Center jointly developed a program to familiarize medical communities with the concept and capabilities of Statewide Trauma Centers and to improve the day-to-day relationships of the trauma centers and the community hospital. The first step of this joint effort, now known as the Trauma Center Outreach Program, was to develop a better understanding of the problems faced by the thirty-one community hospitals located in the 27 county area comprising the base referral area for the two medical centers. The program currently being pilot tested in this 27 county area was designed to assist referring institutions in making rapid assessments and in transferring the small percentage of patients needing resources unavailable at a community hospital. An education program utilizing audiovisual aids and brochures was developed to present to emergency department personnel in the outlying hospitals explaining the function of a Level I Trauma Center, what specific services and resources a statewide trauma center offers, how to efficiently and rapidly contact appropriate personnel within the center to expedite referral and how to select and prepare patients for a safe transfer.

The circumstances relating to the patient transfer and the problems faced by the referring community hospitals were assessed using a questionnaire which was completed by community hospital emergency department personnel. This questionnaire also served to identify staff interest and the perceived need of a trauma education program. Specific questions were included to determine the criteria utilized by the community hospital in transferring patients and patient types always or nearly always transferred. Most importantly, results of the questionnaire would provide information on what the Statewide Trauma Center could do to facilitate the patient transfer and what information the referring hospital would like returned following the transfer. Questionnaires completed by these hospitals indicated that the majority of these institutions always or nearly always transferred serious trauma patients to one of the Statewide Trauma Centers. They indicated a need for additional trauma education, as less than twenty percent of the facilities reported inhouse educational programs on trauma care. Many referring hospitals requested an educational program on preparation of the patient prior to transfer and specific information on what laboratory data or other tests should be done before transfer. All institutions indicated a need for a contact within the trauma center for efficient and rapid patient acceptance and follow-up information.

A grant from the Office of Emergency Medical Services provided the financial impetus to undertake and develop this project. The two hospitals developed an educational packet for state application including a slide presentation on Statewide Trauma Centers, handouts and presentations on the utilization of standardized triage and transfer protocol and a follow-up program. The program identified guidelines directed at early identification of trauma patients requiring transfer to a Statewide Trauma Center, protocols for the treatment of trauma patients prior to and during transfer, organized procedures for facilitating transfer to a Statewide Trauma Center and a timely follow-up system for providing feedback to the referring facility concerning the patient's progress.

Identification of Patients for Transfer

The decision to transfer a trauma patient to a Statewide

From the Department of Surgery, Duke University Medical Center, Durham 27710.

Trauma Center is based on two triage protocols or the diagnosis of injuries requiring special resources. The Trauma Score, developed by Dr. Harold Champion and associates,[1] provides a simple instrument to quickly assess the severity of injury and predict mortality. This system has been widely implemented and found to correlate well with severity of injury and the need for specialized care (figure 1). The Trauma Score is a numerical grading system for estimating the severity of trauma. The score is composed of the measurements of cardiopulmonary function as well as a modified Glasgow Coma Scale. It has been shown that mortality rates increase significantly with progressively lower scores (figure 2). This index allows rapid identification of high risk patients without the need for specific diagnosis.

Another approach to triage is the Anatomical Diagnosis Categories developed by the American College of Surgeons Committee on Trauma. Utilizing this system, patients can be identified as being appropriately cared for at a community hospital (category II or III injury) and those patients with a category I injury who should be transferred to a Statewide Trauma Center (table 1). Modifications in these categories include age (either very young or very old) or preexistent medical conditions; these subclasses of patients may benefit from care at the Statewide Trauma Center.

There are certain injuries that may not be life threatening, but which require the special resources available at a Statewide Trauma Center. These include significant eye injury, soft tissue damage requiring plastic surgery, partial or complete amputation with the need for microsurgical repair or reimplantation, and critical burns. Utilizing the American Burn Association's criteria for disposition of burn patients' critical burns, i.e., those with second degree burns over greater than 25 percent of the total body surface, third degree burns of the face, hands or feet and complications of burns especially respiratory tract injury, should be treated at a special facility.

Trauma Score

The Trauma Score is a numerical grading system for estimating the severity of injury The score is composed of the Glasgow Coma Scale (reduced to approximately one third total value) and measurements of cardiopulmonary function Each parameter is given a number (high for normal and low for impaired function) Severity of injury is estimated by summing the numbers
The lowest score is 1, and the highest score is 16

Respiratory Rate	10-24/min	4	
	24-35/min	3	
	36/min or greater	2	
	1-9/min	1	
	None	0	A =
Respiratory Expansion	Normal	1	
	Retractive	0	B =
Systolic Blood Pressure	90 mm Hg or greater	4	
	70-89 mm Hg	3	
	50-69 mm Hg	2	
	0-49 mm Hg	1	
	No Pulse	0	C =
Capillary Refill	Normal	2	
	Delayed	1	
	None	0	D =

Glasgow Coma Scale

			Total Glasgow Coma Scale Points
Eye Opening	Spontaneous	4	
	To Voice	3	
	To Pain	2	14-15 = 5
	None	1	11-13 = 4
Verbal Response	Oriented	5	8-10 = 3
	Confused	4	5-7 = 2
	Inappropriate Words	3	3-4 = 1
	Incomprehensible Words	2	
	None	1	E =
Motor Response	Obeys Command	6	
	Localizes Pain	5	
	Withdraw (pain)	4	
	Flexion (pain)	3	
	Extension (pain)	2	
	None	1	
Total Trauma Score		(A+B+C+D+E) =	

Figure 1.

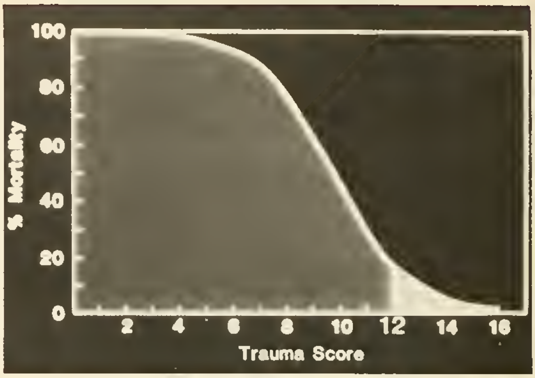

Figure 2.

Treatment Protocols

Once the decision is made to transfer a patient, treatment protocols have been developed to insure proper stabilization and safe transfer. Important aspects of these treatment protocols include airway stabilization and maintenance through the use of endotracheal or cricothyroidotomies with oxygen therapy, the use of adequate fluid prior to and during transport to maintain blood pressure of at least 90 mm Hg, and the use of MAST trousers to augment fluid resuscitation (figure 3).

Specific injuries require additional therapeutic maneu-

Table 1
Anatomical Diagnosis Categories

CATEGORY I PATIENTS

combined system injury	severe maxillofacial injuries
open fracture	unstable chest injuries
uncontrolled hemorrhage	pelvic fractures
blunt abdominal trauma with hypotension	penetrating abdominal wounds
neurological injuries unconsciousness posturing paralysis	severe head, neck and upper respiratory tract injuries

CATEGORY II PATIENTS

open or closed fractures	multiple rib fractures
soft tissue injuries with stabilized bleeding	blunt abdominal trauma without hypotension
transient loss of consciousness	

CATEGORY III PATIENTS

uncomplicated fractures	no neurological injuries
no hypovolemia or hypotension	chest injuries without respiratory distress

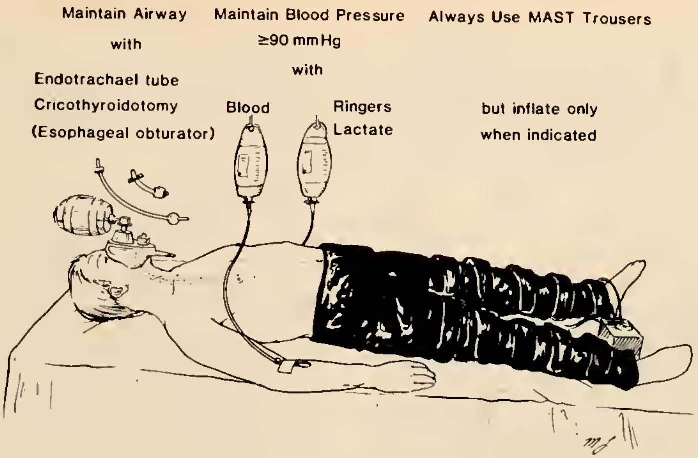

Figure 3.

Transfer Flow Chart

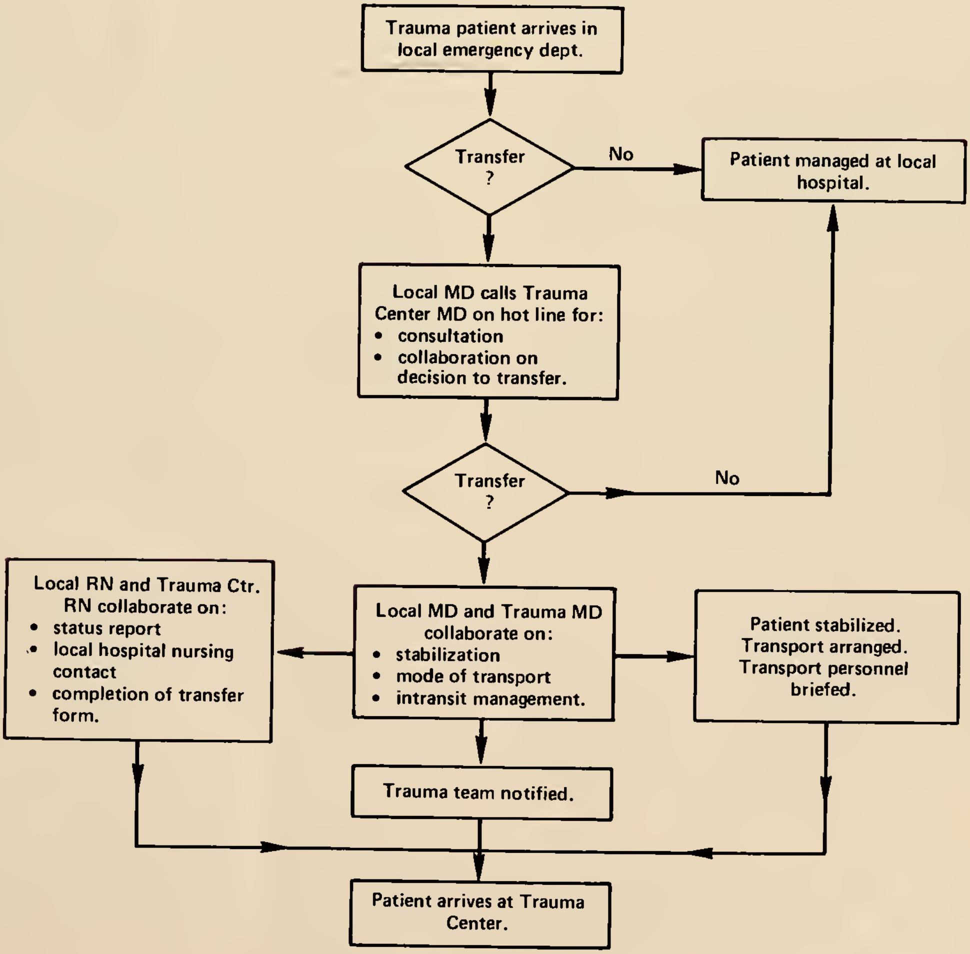
Trauma patient arrives in local emergency dept.
Transfer ?
No
Patient managed at local hospital.
Local MD calls Trauma Center MD on hot line for:
• consultation
• collaboration on decision to transfer.
Transfer ?
No
Local RN and Trauma Ctr. RN collaborate on:
• status report
• local hospital nursing contact
• completion of transfer form.
Local MD and Trauma MD collaborate on:
• stabilization
• mode of transport
• intransit management.
Patient stabilized. Transport arranged. Transport personnel briefed.
Trauma team notified.
Patient arrives at Trauma Center.

Figure 4.

vers prior to transport. Neurologic injuries should receive ventilatory support, stabilization with a cervical collar, back immobilization and nasogastric decompression. Chest injuries with specific complications such as hemopneumothorax may require chest tube placement. Flail chest requires ventilatory support and cardiac tamponade requires pericardiocentesis. These treatment protocols also contain information on stabilization of abdominal, soft tissue and burn injuries.

Transfer Procedure

Transport should be arranged once initial stabilization is begun. During the transport phase, continued care should be provided. In order to facilitate and provide consultation for the initial stabilization and transfer, special telephone lines have been installed in the emergency departments of both Duke University Medical Center and North Carolina Memorial Hospital to handle communication pertaining to trauma patients requiring transport to these centers. These telephones (DUMC 1-800-672-2538 and NCMH 1-919-966-3333) are manned 24 hours a day by a physician with trauma care skills. This allows direct physician-to-physician contact early in the trauma patient's treatment course.

As the transfer is evolving, the goal should be continued support of the respiratory and circulatory systems during transport. Adequate volume replacement during the transfer, continued monitoring of vital signs and use of appropriate drugs are emphasized. Additional communication with the Statewide Trauma Center by phone allows periodic updates on the estimated time of arrival and any significant changes in the stability of the patient (figure 4).

Follow-Up System

One of the important outcomes of the Trauma Center Outreach Program was the development of a system to provide feedback to the referring physician concerning the patient's progress. Previously, patient information including discharge summary was often sent to the patient's primary physician. Under the new follow-up system (figure 5), information will be provided both to the patient's primary physician as well as the emergency department physician who referred the patient. This allows communication between the referring emergency department and the Statewide Trauma Center, thus reinforcing the effectiveness of the triage and treatment protocol.

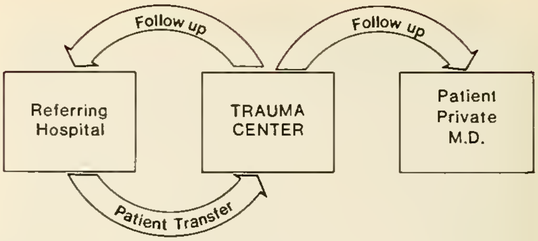

Figure 5.

Future of the Trauma Center Outreach Program

At the present time, programs have been presented to approximately two-thirds of the community hospitals in the North Carolina Memorial Hospital and Duke University Medical Center referral catchment area. An extensive evaluation process of the demonstration program has included evaluations of the educational presentations for their organization, content and effectiveness; the ability of the program to increase the number of critically ill and injured patients who are appropriately stabilized and managed; the overall effectiveness of feedback provided to the referring hospitals; and the success of increasing the confidence with which trauma patients are transferred.

Based on this evaluation, alterations are being made to improve the program and eventually disseminate it for use by other trauma centers within both North Carolina and other states. The ultimate goal of this program is to provide the nurse and physician in the emergency department with the information they will need in order to readily identify those individuals who can best be cared for in a Statewide Trauma Center as well as increasing the accuracy and confidence with which the emergency department personnel make this judgment.

Reference

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SCIENTIFIC ARTICLE

Trauma Care Delivery in Eastern North Carolina

Larry S. Lewis, M.D.

• *A presentation of the options for improving care of trauma victims in the rural parts of Eastern North Carolina.*

IN recent years, trauma has become recognized as a major national health problem and economic burden. What has not been adequately emphasized or appreciated is the component of this problem contributed by rural areas. Although 70 percent of the nation's population now lives in urban areas, up to 70 percent of our trauma fatalities still occur in rural areas.[1] The fatality rate for rural motor vehicle accidents remains four to six times that of comparable urban injuries.[2-4]

Eastern North Carolina, a primarily rural 29 county area with a population of 1.5 million, certainly shares many common problems with other rural sectors of the United States: 1) long distances from regional trauma facilities; 2) access to emergency transport capabilities; and 3) preparedness of local physicians in early care of the injured patient.

The Pitt County Memorial Hospital and the East Carolina University School of Medicine and their staffs have recently assumed the responsibilities of the Level II Trauma Facility for this underserved region. The responsibilities of this require that we address the above concerns.

The geography of eastern North Carolina does little to aid in the rapid and efficient delivery of emergency trauma care. Large distances are frequently involved from the site of injury to the place of initial care. Injuries frequently occur in isolated settings where both communication and transportation are impeded. The routes of travel are far from the super highways of the urban setting. This all serves to delay the early care of the injured patient and certainly interferes with rapid ground transportation to higher level trauma facilities.

Two possible solutions to this problem immediately come to mind: 1) air evacuation; 2) improved ground transportation.

The first of these, air evacuation, has some positive and negative aspects. On the positive side, many studies have been reported in the literature attesting to improved survival statistics for the air evacuated patient but these are frequently difficult statistics to evaluate in terms of comparable patients handled by ground transportation. In addition air transportation may serve as an important patient referral source, a clear positive in this era of competition for a decreasing patient census.

On the negative side, high start-up and operating costs are the major deterrents to initiation of this service. The first step that any hospital should take before establishing an emergency helicopter service is to conduct a thorough feasibility study. This study should include an analysis of projected utilization, a review of clinical resources and an evaluation of costs.

Approximately 70 percent of the cost of operating a helicopter service is fixed, so it is essential for the hospital to maintain a minimum number of flights. Each hospital must carefully survey its own situation prior to instituting a helicopter service.

The second drawback, ground transportation, also involves large capital outlays, but no single source is required to bear the burden so these costs are more easily distributed. In addition it can expand in small increments once the basic framework is already in existence. The main disadvantages of ground transportation are access to the injured and time of transportation.

Although there may be some disagreement regarding the best form of transportation there is little question regarding the most important ingredient for future expansion and growth of eastern North Carolina's regional trauma care: the wider and mandatory certification in Advanced Trauma Life Support, as outlined by the American College of Surgeons. Currently there remain deficiencies in the early care and treatment of the injured whether one works in the large or small hospital. We can all improve our performance through proper application of the techniques outlined in the ATLS course. Making this a requirement for all physicians working in emergency departments would not only enhance care of the critically injured but would also improve care of the less severely injured and perhaps lessen the overall morbidity of trauma and deliver a more stable and potentially salvageable patient to regional care facilities.

Our main emphasis is placed on physician education. Neither air nor ground evacuation is as rapid and smooth as portrayed, and both require sophisticated support. Both are only as good as the initial triage and treatment allow. All injured patients would benefit from a better trained, more sophisticated physician population. Lastly, better injury care is still only as good as the human component.

We should not be caught up in the glamour of high speed transport and fancy equipment and lose sight of the multitude of lesser injuries that exact a large cost to our state, in both monies and suffering, but instead should build a sophisticated regional trauma system based on good initial care and an expedient long distance transport.

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From East Carolina University School of Medicine, Greenville 27834.

SCIENTIFIC ARTICLE

The Interagency Incident Management System: An Important Element in Successful Prehospital Emergency Medical Care

Herbert Garrison and Thomas Griggs, M.D.

• *This paper describes a simple interagency incident management system that provides for the safety of emergency personnel as well as for planning and coordination of resources at emergency scenes. Control and coordination provided in this manner can mean the difference between life and death to both patients and rescuers.*

THE prehospital care of trauma patients in North Carolina has improved greatly in the past ten years. In many localities, emergency medical technicians are capable of performing sophisticated medical procedures including volume resuscitation and advanced cardiac life support. The training of these technicians has been predominantly technical and has been provided in large measure by medical professionals. Many, if not most, of these trainers have had little or no experience in providing prehospital care. Those who have functioned to some degree in the field have been impressed with the difficulty of controlling the emergency scene so that patient care can proceed as it is expected to in a hospital setting.[1] The need to gain and maintain control of the emergency scene is, therefore, becoming recognized. Unfortunately, the mechanisms by which such control can be achieved are not widely known nor practiced. This paper will illustrate efforts in Orange County, North Carolina to develop and use a simple incident management scheme. It is designed to be used by all of the emergency agencies in the county to provide the control and management in the field that is recognized to be the crucial first step in determining the eventual outcome of patients involved in emergencies.

Case Illustrations

The need for management at the scenes of emergencies can be illustrated to some degree by the following case reports.

The most critical goal of a scene management system is to provide safety for the emergency medical and other emergency personnel working with the emergency. Many examples can be given to describe tragic accidents occurring to emergency personnel as a result of their unknowing entry into hazardous environments.

Case 1: An ambulance was summoned to the basement of the Pharmacy School on the campus of the University of North Carolina at Chapel Hill. The caller reported that she thought a victim had suffered a heart attack and was unconscious. Upon arriving at the scene, the two paramedics entered the basement of the building as directed by bystanders and found a male patient on whom two occupants of the building were performing cardiopulmonary resuscitation. Immediately upon the arrival of the ambulance team, the citizen rescuers stepped back, reported that they were ill, and staggered from the building. The paramedics began immediately to assess the patient and to continue cardiopulmonary resuscitation. They noticed a strange odor in the room, and they quickly developed headaches and nausea. Within a few minutes, a safety officer from the University entered the building wearing self-contained breathing apparatus. The patient was successfully resuscitated from ventricular fibrillation and transported to the hospital. The paramedics were ill for a short period but recovered without treatment.

Review of the incident indicated that the patient had been the victim of a large chloroform spill that had occurred in a room only several feet from where the paramedics assumed his care. The fact of the spill had not been reported to the person who in turn called the 911 emergency operators.

Failure to assign responsibility for safety at the scene to one paramedic could have, in this case, cost both of them their lives. Under the Orange County incident management scheme, the first arriving emergency unit at an incident assumes "command." The first task of command, in turn, is to view the scene and to make other observations and determinations as necessary to insure the safety of all of the emergency personnel on the scene or reporting to the scene. Subsequently arriving units allow this assessment to be made by assuming a "staged" position several hundred feet from the scene until assigned to duties at the scene by the command person. Assumption of command by standard procedure, assigning security functions to command as a high priority responsibility, and supporting the safety and security priority by the use of staging for subsequently arriving personnel allows control at a scene to be established as an initial event.

From the Division of Cardiology, University of North Carolina School of Medicine, Chapel Hill 27514.

Case 2: The second major goal of an incident management program is to coordinate activities so that people and other resources are used as efficiently as possible. This requires the development of a plan or strategy, and the deployment of people and equipment according to that plan. The following case represents an example of the need for such a plan.

A small, single engine aircraft with four passengers and a load of fuel and luggage attempted to depart from the Horace Williams airport in Chapel Hill. The plane developed insufficient power to clear the runway, banked to the left, and crashed nose down into a field. The crash was witnessed, and rescue, fire and police agencies were dispatched. The crash caused major injuries to all four occupants of the plane. The injuries involved head trauma as well as major chest, abdominal and extremity injuries. Several paramedics, additional emergency medical technicians, police personnel trained and certified as emergency medical technicians, and two physicians were at the scene within several minutes. Extrication progressed rapidly. The patients were then placed in an area where they were separated by the airplane debris and by distances of up to 50 feet. Medical equipment was scattered throughout the scene. Devices such as blood pressure cuffs were moved from one patient to the next. The two physicians made rapid evaluations on two of the patients but knew nothing of the conditions of the other two. The patients were treated by the EMTs and paramedics who first encountered them. No effort was made to establish by priority the order of transport of the patients, and the physicians at the scene were used ineffectively. Finally, considerable problems occurred with transport because police officers were unable to assume that they had permission to ride with patients in the ambulances.

This case illustrates a common event in emergency medicine. A major accident occurred and caused a number of serious injuries to a relatively small number of patients. Sufficient manpower and equipment were at the scene within minutes, yet they were used less effectively than appropriate.

Many authors have written of the need for a special strategy for managing major incidents such as this.[2, 3] That strategy involves four main elements: 1) "triage" to identify salvageable patients with need of immediate care, 2) "extrication" from the immediate incident scene to a treatment area in a centralized place, 3) "treatment" in the field treatment center, and then 4) "transportation" of the patients according to a priority based upon the extent and survivability of their injuries. Unfortunately, such a strategy requires judgments based upon good management procedures. In many communities, as in ours at the time of this incident, the knowledge of such a strategy fails to bring about the implementation of the strategy. This is because no system is in place to provide for a person who 1) will make the decision that that strategy will be followed, and 2) will gain control of incoming resources so that they can be deployed according to that strategy. In the system now in place in Orange County, the command officer's function is to establish a simple "strategy" or plan and then to support the plan by placing people into manageable teams and assigning them definable tasks. To establish a strategy, the command person is expected to consult with as many people as necessary. In fact, in the situation described above, the command officer would probably have been a fire officer who would have appointed a medical officer to establish medical strategy and set it into operation. The teams, in turn, would have been formed in a staging area and then deployed in "sectors," probably named "extrication," "treatment," and "transportation."

The Incident Management System

The incident command or management system adopted in Orange County is patterned after that used by the National Interagency Incident Management System.[4, 5] The Orange County incident management system is based upon a set of standard operating procedures used by essentially all of the emergency agencies in the county. The standard procedures outline the following basic components of the system:

1) At every incident where more than one agency responds, the first arriving unit is responsible for establishing command. Command, obviously, may then be transferred up a chain of command as appropriate. However, the designation of command implies that throughout the emergency, the functions of management will be focused on one individual.

2) The system further provides that the function of this management program is to provide for what we call "the five S's" — 1) security, 2) staging, 3) strategy, 4) sectors, and 5) support. The case illustrations describe the characteristics of the first four of these functions. The provision of support in the management system involves supply, communications, public relations, and other elements that may be needed as resources to manage an emergency incident smoothly and efficiently.

The establishment of the system in Orange County has evolved over several years after initial stimulation by discussions of incidents such as those described above. These discussions involved not only emergency personnel but community management and political leaders as well. The medical community and specifically the Disaster Committee of the North Carolina Memorial Hospital were deeply involved in the planning and practicing that led to the establishment of the system. The program now is coordinated by the county's Emergency Services Director. This person chairs a committee referred to as the "Command Team." This team comprises the chief and assistant chiefs of every emergency agency in the county, the elected officials, the county and town managers, and the emergency department and security chiefs from the hospital. The team meets as a whole at least every two months. The team includes, as well, several subcommittees, which meet more frequently. The meetings involve critiques of incidents, training in command functions, and planning. The command team also coordinates at least four major disaster drills each year and sponsors command and mass casualty management programs that are presented as training units to the individual agencies on a regular basis.

The incident management program has affected all aspects of prehospital emergency care in Orange County. Its major effect has been to bring about better cooperation and coordination between the agencies. A single case illustration makes this point.

Case 3: A college student and her boyfriend were arguing violently in a local apartment house. The girl's brother came to check on her and in an ensuing argument was shot in the abdomen. The assailant fled to a nearby apartment. The dispatch center dispatched police and rescue units. The first public safety officer on the scene reported that he had a victim and a witness who had seen the assailant in the area with the gun. He established command and advised the rescue unit to stage one block away. By way of radio, he then deployed a team of officers to secure the apartment where the victim was reported to be. Those officers, having been assigned by command, then reported the apartment secured, asked that the rescue unit be sent forward, and remained with the rescue unit while paramedics assessed and treated the patient. A second team of officers was assigned to pursue and arrest the assailant. This was accomplished within several minutes. Further responding officers were asked to secure the streets in the area and to deal with the neighbors who by this time were beginning to assemble. Command was transferred within a few minutes to the police patrol supervisor who secured the crime scene as the victim was removed and called for investigators and photographers.

This case illustrates the functions of security, staging, strategy, sectors, and support. It also demonstrates the important coordination and cooperation aspect that an interagency incident management system can provide.

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North Carolina Medical Journal

Features for Patients November 1984

SEAT BELTS PAY OFF

B. J. Campbell, William Hunter, and Marianne Gemming

Did you know that a seat belt can save your life? Did you know that wearing belts can win you prizes?

A research project applying behavior theory was conducted in Chapel Hill and Carrboro to increase the use of vehicle safety belts. The Highway Safety Research Center at UNC was funded to determine whether a widely advertised seat belt campaign combined with various incentives would result in greater seat belt usage.

Seat belts are the single most cost effective way to reduce motor vehicle deaths, the leading cause of death for all persons under 34 years of age.[1] North Carolina crash data show that death among front seat passenger car occupants is reduced by 60-65% among belted compared with unbelted occupants controlling for severity of the crash. Likewise, serious injuries are reduced by about half when occupants are properly restrained.[2]

Yet belt use has never been very high in the U. S. Nationally, belt use is now estimated at 13%.[3] In North Carolina, use among crash victims is about 5%.

To date, efforts to increase use through publicity campaigns have not shown much success although, to be fair, not a great deal of resources have been devoted to this in the past.[3] In contrast, nearly 30 other countries and states have traffic laws requiring belt use,[4] much like recently enacted child restraint laws now in force in 46 U. S. states.[5] In most foreign countries with belt-use laws, belt use is quite high. In Australia, belt use in Melbourne is over 90% in the daytime urban setting, and is never much lower than 60%.[6]

SEAT BELTS PAY-OFF

A contest logo and slogan were used throughout the campaign. The message was "Seat Belts Pay Off" in lives saved, in injuries reduced and, during the campaign, in contest prizes.

Growing out of the work of B. F. Skinner, the idea of using rewards to strengthen behavior has by now had countless applications. The idea of randomly rewarding belt wearers has been tried in several closed settings like high schools or factories. Indeed, in 1982 a project at the Chapel Hill High School achieved a maximum 70% wearing rate based on the random allocation of 300 five-dollar prizes.[7] Even at the end of the school year belt wearing rates held at 45% (up from a baseline of 19%). Rates have held for this school year at 45-50% by the once-a-week allocation of rewards donated by parents and the PTA. A 52% shoulder belt wearing rate was seen the final week of school. Based on previous data, we estimate that added lap belt use brings the total restrained to 60% or

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From the Highway Safety Research Center, University of North Carolina Statewide Trauma Center, Chapel Hill 27514.

greater. Similar results have been demonstrated in 10 or so other work place settings.

The idea of the current project was to learn whether the same techniques will work in the much larger setting of a whole community, where it is more difficult to make people aware of the campaign and therefore more difficult to reinforce the benefit to belt wearing. In a setting like a school or factory essentially everyone knows about the effort, and also nearly everyone will repeatedly see the incentive-giving team at work near the factory or school gates. In the community at large, both of these elements are less of a factor. To test this hypothesis, in a campaign entitled "Seat Belts Pay Off," vehicles were stopped at random at safe places out of traffic, and belted occupants were given a modest prize (such as a free meal) donated by local businesses and other organizations. Each winner was also given an entry blank for a $500 monthly drawing and a $1000 grand prize. Television and radio spots were aired daily, and newspaper coverage included editorial support for efforts to induce belt wearing.

About 50,000 copies of a brochure proclaiming the importance of seat belt use and the "Seat Belts Pay Off" campaign were distributed in the community. Further, the campaign received the endorsement of the University and the two town governments as well as several civic organizations.

Baseline data were collected at 17 major traffic locations with about a 24% wearing rate observed, about twice the national average. Observers collected experimental data on a weekly basis using a seven-level, stratified sample design. Observers beside the road counted shoulder belt use in passenger cars having head restraints. (Cars too old to have head restraints are very unlikely to have shoulder belts.) Since some drivers still wear lap belts only, our figures underestimate somewhat the actual number restrained. We did not count utility vehicles, pickup trucks, or vans for data collection purposes, because many of these vehicles do not have shoulder belts. However, for purposes of giving out incentives, all of these vehicles classes were included (since only the lap belt need be worn to win a prize).

During the six month campaign we observed an average weekly belt use increase from 24% baseline to 41% in the final week. Wearing rates among women were a bit higher than among men — about 2 percentage points. The wearing rate among whites was about fourfold higher than among non-whites, a most serious finding in regard to factors involved in obtaining true community-wide success. Even six months after the end of the campaign, belt use is still 36-39%.

The absence of seat belts ranks with drunk drivers as one of the two factors associated with the most highway deaths. Progress in controlling drunk drivers is very expensive and also rather uncertain because of trying to control the deviant behavior of many drivers for whom alcohol is a significant medical/behavioral problem. In contrast, increasing use of seat belts is a matter of inducing a normal behavior among members of the mainstream population. In view of this, it is clear that success in increasing belt use will have high payoff at minimum cost.

Traffic crashes are the leading cause of death for age groups under 34 years old. Yes, the leading cause, ahead of all other causes. For those over 34, crashes are still a major cause of death. We may dismiss those statistics because riding in a car feels so safe. And that's right. Trip by trip it is pretty safe, but in years of driving the chances of a serious crash are great. Buckling up when you ride is

Belted occupants of randomly stopped cars received educational materials, a small prize (or coupon for a prize) and a chance in cash drawings.

the single most effective thing you can do to increase your chances of escaping serious injury or death in a crash. Belts can save 200 of every 300 now dying unbelted and can reduce serious injuries too. That can translate into hundreds of lives saved each year in North Carolina. Not wearing seat belts results in as many highway deaths as drunk drivers cause.

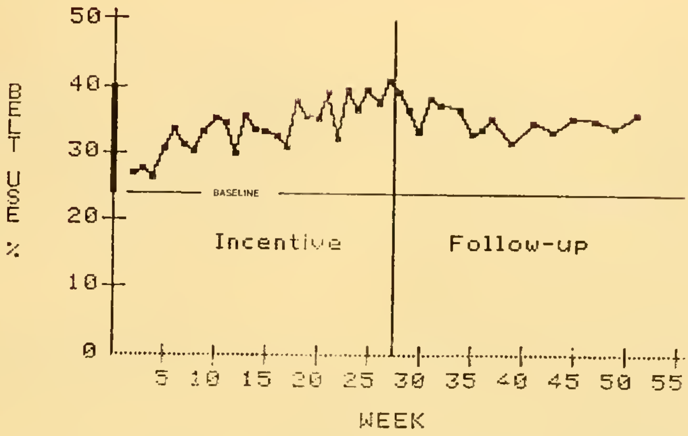
The bad news is that in the U. S. only about 10% of people buckle up. Why so low? People give lots of excuses for not wearing belts, some based on dangerous myths.

"It's better to be thrown clear of the car."

NO, in fact it is many times worse. "Thrown clear of the car" often means being thrown through broken glass, onto the pavement, or into the path of another car.

"My car might catch on fire and I'd be trapped."

NO, odds are thousands to one it won't catch fire. *AND,* if quick escape is necessary, you are more likely to be conscious and able to get out of the car if you are wearing your seat belt. Maybe the main reason we don't wear belts is that we just don't think about it. Why not start your community thinking about it. Start your own community project. It worked in Chapel Hill. Contact your local police and civic leaders. Additional information may be obtained by contacting the University of North Carolina Highway Safety Research Center.



Belt use increased steadily during the incentive campaign, reaching 41% the final week. Once the contest ended, belt use slipped but stayed at 36% — a substantial net gain involving several thousand drivers.

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Canker Sores, Aphthous Ulcers, Mouth Ulcers

Claude S. Burton, M.D., Russell W. Eyre, M.D., and J. Lamar Callaway, M.D.

We may not all use the same name for mouth ulcers but we all agree mouth ulcers are terribly painful. Hippocrates called mouth ulcers Aphthae and the term has remained in medical jargon. For those unfortunate enough to experience repeated attacks, mouth ulcers are a disaster. During an attack a person is often unable to eat, drink, or even talk. The pain may be severe enough to interfere with sleep and is always bad enough to affect one's disposition. Many people have consulted us over the years for advice and we would like to share our experience with all who are interested.

Conservative estimates suggest that at least 20% of the American population will be affected, usually by the age of thirty. Attacks are often precipitated by trauma (biting the tongue or cheek, dental work, etc.) and in many women a striking association with menstrual periods has been noted. Allergy to various foods appears to be responsible in some cases and many patients believe stress is a factor. Certainly having a crop of ulcers is a stressful situation!

The ulcers are found throughout the mouth. Clinical features may be divided into four stages but keep in mind that not all patients are typical. During the first stage there is usually pain or tingling in the mouth though the mouth looks normal. In about 24 hours the preulcerative stage (stage II) begins with the appearance of a red bump at the site of earlier symptoms. 18-72 hours later the third stage begins as the surface of the bump is sloughed, forming an ulcer or small crater in the mouth. The ulcer is often exquisitely painful, even to the slightest touch, and may be equally sensitive to the presence of foods and liquids. At this stage the movement of the tongue during talking may be so painful that conversation is avoided entirely. The ulcer stage lasts from 1-16 days until the ulcer is covered by a gray or yellowish membrane. Shortly after the membrane appears, the pain abruptly ceases and the healing stage (stage IV) begins. The ulcers usually heal without scarring within two weeks. With deeper ulcers there may be scarring. As indicated above, the time course is highly variable and the disappearance of pain rather abrupt. This variability confounds the study of various therapeutic strategies.

In most cases the cause is unknown and despite the most complete of investigations the cause will not be discovered. Doctors call such cases "idiopathic" which is medical jargon for "I have no idea what is causing this" or, jokingly, "the doctor is the idiot, the patient has the pathology." More importantly, the term idiopathic implies that the doctor has considered the known causes of the problem and carefully excluded them on the basis of information gleaned from the history, physical examination, and in some cases, laboratory investigation. A number of known causes of mouth ulcers must be considered, particularly in people with recurrent attacks.

Occasionally mouth ulcers indicate an underlying disease. Deficiencies of iron, folate, and vitamin B12 have all been associated with mouth ulcers and where such deficiencies were identified, patients have responded well to replacement therapy. Since iron, folate, and B12 are essential for the formation of blood, one can easily assess body stores of these substances by looking at a sample of blood under the microscope. For definitive diagnosis, a specimen of bone marrow may be examined under the microscope or levels of these vitamins in blood may be measured. If still in doubt, a therapeutic trial with these agents may be warranted.

Several diseases of the bowel are associated with mouth ulcers including ulcerative colitis, regional enteritis, and gluten sensitive enteropathy. A discussion of these diseases is beyond the scope of this article. However, if symptoms such as diarrhea, weight loss, abdominal pain, and anemia are associated with mouth ulcers, these diagnoses must be considered. Gluten sensitive enteropathy (GSE) is an illness related to a wheat allergy. Several patients with GSE and mouth ulcers without bowel symptoms have been reported. In these cases a wheat-free diet has been helpful.

When genital ulcers and mouth ulcers are both present an illness known as Behcet's syndrome must be excluded. Behcet's syndrome is associated with pains in the joints, inflammation in the veins leading to thrombophlebitis, and rare more serious complications. Of particular concern is a destructive eye disease associated with Behcet's syndrome. Where this diagnosis is considered we recommend ophthalmological consultation.

The vast majority of cases remain unresolved. Cultures for bacterial or viral agents have generally been negative leaving the impression that aphthae were not related to infection. These early studies may have thrown investigators off the track since new, more sensitive techniques now suggest that a virus may be responsible for causing the disease. A recent study demonstrated the presence of herpes virus products in biopsy specimens of mouth ulcers despite the fact that viral cultures were negative. The authors of the study suggest that the host response to the virus leads to ulceration.

If there were a cure, I doubt there would be sufficient interest to justify this article. Unfortunately there is not. If the evidence for a viral cause is further substantiated then perhaps vaccinations or the newer antiviral drugs will have a dramatic impact on this disease. Pending such an advance, the following approach will be helpful. After excluding the above causes we ask patients with recurrent mouth ulcers to keep a diary in the hopes of ferreting out that rare individual with a clearcut allergic cause. If every time a person eats peanuts he or she gets ulcers, then the cure is obvious.

Topical anesthetics such as viscous xylocaine will relieve pain and allow eating and talking but must be used with certain cautions. If the anesthetic spreads to the throat then the gag reflex that protects us from choking may be lost with potentially dangerous consequences. A medicated mouthwash containing a mixture of steroid, tetracycline, and the antihistamine diphenhydramine (Benadryl), is useful in many cases. Prednisone tablets are often dramatically effective. Though prednisone tablets have innumerable side effects if they are taken continually, the short term treatment of aphthae rarely if ever causes any difficulty. We advise select patients to take 1 mg/kg at the first sign of trouble and for two days thereafter. On this regimen many attacks never get off the ground. Topical steroids are an alternative but are difficult to use inside the mouth. Interestingly, like warts (which are known to be caused by virus), hundreds of folk remedies are anecdotally effective. One of us has a sister who swears by a tiny Panamanian pebble carried just inside the cheek!

MEDICAL EDUCATION

Activities of the North Carolina Committee on Trauma of the American College of Surgeons

Robert W. Youngblood, M.D.

• *The Committee on Trauma aims ultimately at preventing serious accidents. It sponsors a training program for doctors and nurses on acute care of traumatized patients and also collects data on the epidemiology of trauma.*

TRAUMA is the leading cause of death in the United States in the first four decades of life. It is exceeded only by heart disease and cancer in number of deaths in the entire population of the United States. The peak incidence of trauma deaths and disability is between the ages of fifteen and twenty-four. Thus, trauma affects our young, most productive citizens, causing death, disability and loss of productivity exceeding an estimated seventy-five million dollars per day. Approximately fifty percent of trauma deaths are caused by motor vehicle accidents, and all too frequently alcohol and drugs are significant contributing factors to the accident. Approximately twelve percent of the hospital beds in the United States are occupied by victims of injury. The primary efforts of the Committee on Trauma of the American College of Surgeons is to foster the optimal care of the traumatized patient.

The ultimate goal in the management of trauma is prevention. However, once an injury has occurred, optimal care consists of the re-establishment of normal physiologic processes in the most expeditious manner, with the least threat to life and without permanent disability. This consists of stabilization of the patient with management of his airway, treatment of shock, stabilization of fractures in the field and rapid transportation to a facility competent to manage his injuries. Included in such a system is a trained paramedical team for field stabilization and transportation, a communications system to alert the treatment facility and an organized and trained team to manage the patient expeditiously following his arrival at that facility.

The North Carolina Committee on Trauma of the American College of Surgeons has worked closely with the Office of Emergency Medical Services in an effort to obtain the best care for the trauma patient. Since 1981 this Committee has sponsored a training program, Advanced Trauma Life-Support (ATLS), in an effort to train physicians and nurses in the resuscitation and initial treatment of the injured. This is an intensive two day course consisting of a series of ten lectures, skill stations, animal laboratory, case studies and initial assessment of moulage patients. The student/faculty ratio is approximately three to one. In the past three years twenty-six such courses have been held for medical providers in North Carolina. This included two courses for medical students and three courses for surgical housestaff at teaching institutions. Additionally, three courses to train ATLS instructors have been given. A total of 58 instructors and 449 providers have been trained. Because of a strong belief in the team concept in the management of trauma, emergency room and critical care nurse courses have been given in conjunction with some of the physicians' courses to train nursing personnel in Advanced Trauma Life-Support. The thrust of this training is to establish a system of prioritization and to teach techniques for recognizing and managing life threatening and potentially disabling conditions. Such an intensive training program for those who are in the front lines of emergency care should result in a further lowering of mortality and morbidity for the injured.

On a time scale the first peak of trauma mortality is within a few minutes of the injury. This usually involves those individuals who have suffered brain laceration, a high cervical cord injury or major disruption of the heart or great vessels. These persons generally die at the scene of the accident and very little can be done in injuries of this magnitude which cause such rapid demise. The second peak of deaths on a time scale occur in those patients with severe injuries which rapidly progress to disrupt vital physiologic functions. Such injuries are expanding intracranial hematomas, airway obstruction, flail chest, sucking wounds of the chest, pericardial tamponade and bleeding from ruptured viscus or from major vessels. These patients may die within minutes to hours following their injuries but are salvageable if an efficient system of trauma management is available. It is these patients to whom the advanced trauma life-support training is directed.

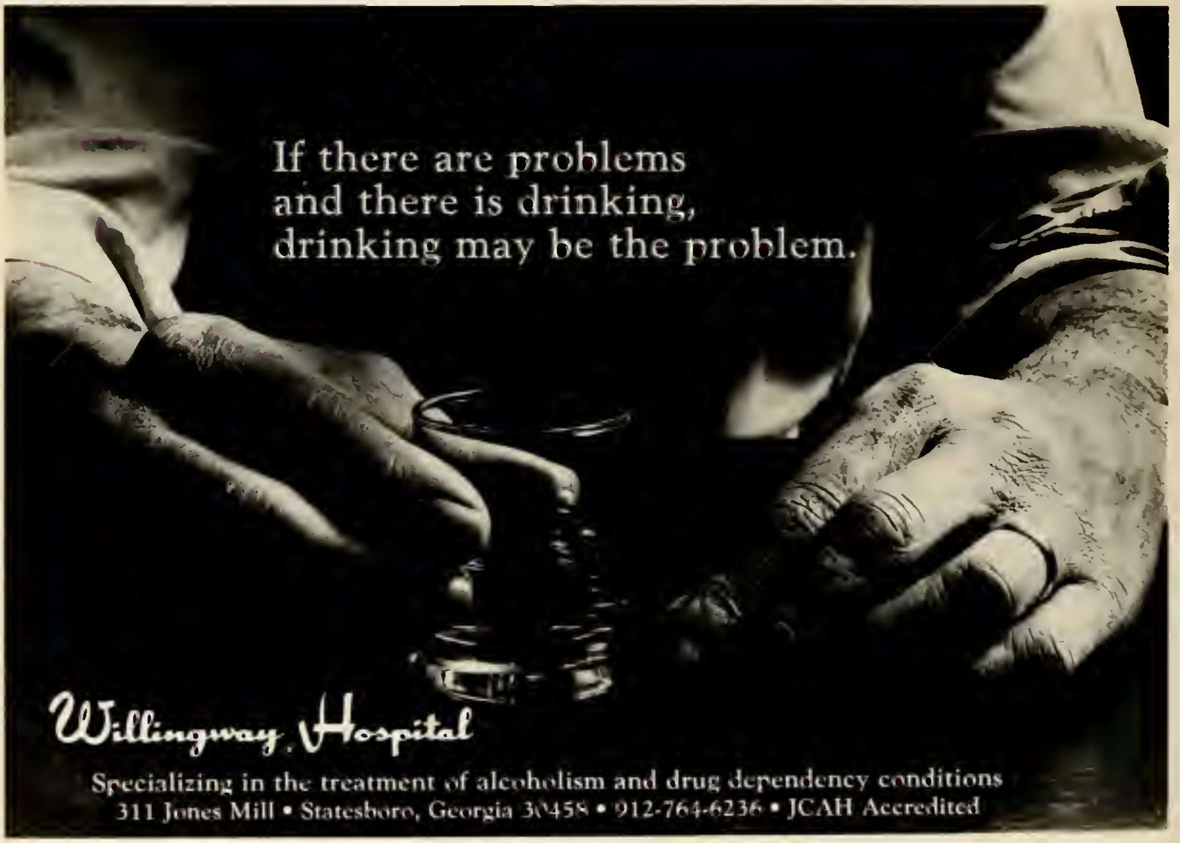
A second major area of interest of the N. C. Committee on Trauma is the epidemiology of trauma. Presently, there are few hard data on the incidence or severity of trauma in North Carolina. Stemming from the impetus of the N. C. Committee on Trauma, a study is presently being completed to evaluate the incidence of severe trauma and burns so that statistics might be available in planning the number of trauma centers necessary to serve citizens of North Carolina. This study has shown that an estimated 3,500

From Wilson Clinic P.A., Wilson 27893.

patients annually are severely injured. The North Carolina Committee on Trauma is seeking to establish a Trauma Registry so that prospective statistics may be obtained, not only for the incidence of injury, but for the outcome of these patients to establish trends and to outline the ideal management of the injured.

At one time the objective of the trauma surgeon was to "do no further harm." The time has come when we must look toward this dictum as being obsolete and strive for a system where, once the initial damage of the patient's trauma has been completed, that person can look toward a course of continuing improvement with recognition of his injuries, management of the life threatening situations and a continual improvement with lessening of risk of mortality and disability from the time he first finds paramedical assistance through his treatment and complete rehabilitation.

The ideal in trauma management is prevention. With the active support of the N. C. Committee on Trauma, the State of North Carolina is seeking to do this with legislation to try to rid our highways of those who are driving while impaired. We hope to lessen the severity of injuries with the use of seatbelts, as well as helmets for motorcyclists. When prevention fails and major injury occurs, we are attempting to establish a system of field stabilization with trained paramedical personnel, expeditious transportation to a facility capable of managing the patient's injuries and a communications system which allows for emergency department alert to anticipate the needs of the trauma victim. We, as physicians, have a duty to the citizens of North Carolina to foster prevention, to establish an expert emergency medical system, to equip our hospitals and to train ourselves to seek the optimal care of the injured.



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EDITORIAL

The University of North Carolina — North Carolina Memorial Hospital Statewide Trauma Center: How to Make Bricks Without Straw

H. J. Proctor, M.D.

> *"And Pharaoh commanded the same day the taskmasters of the people, and their officers, saying, Ye shall no more give the people straw to make brick, as heretofore: Let them go and gather straw for themselves. And the tale of the bricks, which they did make heretofore, ye shall lay upon them; ye shall not diminish ought thereof:"*
> *Exodus 5:6*

THE North Carolina Memorial Hospital is the major teaching hospital of the University of North Carolina School of Medicine and has, since its opening, served as a major referral center as well as a primary care resource for the area immediately surrounding Chapel Hill. As the population of North Carolina increased along with the speed limit, the popularity of alcohol and drugs, and a fondness for firearms, the number of trauma victims increased. In response to this increase in trauma admissions and to provide better patient care and better resident and medical student education, the University of North Carolina and the North Carolina Memorial Hospital became a self-proclaimed trauma center in 1972. Similar pressures brought about the creation of trauma services at Duke University Medical Center and the North Carolina Baptist Hospital.

An estimated 7,000 individuals per year are injured or burned in North Carolina badly enough to require hospitalization; nearly half of them have a trauma score of 12 or less indicating the desirability of admission to a major trauma center.[1] At the same time these data were becoming available, a requirement of the federal Emergency Medical Service Systems Act was the formal designation of trauma centers. Three level 1 or statewide trauma centers were designated, the North Carolina Memorial Hospital, Duke University Medical Center, and the North Carolina Baptist Hospital.

Although on a given day in the hands of a given surgeon any hospital can provide excellent care for the traumatized patient, what differentiates a trauma center from a non-trauma center is uniformity of a given capability (prescribed as part of the designation process) 24 hours per day, seven days per week. Perhaps the major determinant that sets the trauma center apart is an institution wide, multidisciplinary commitment to trauma care.

Specialized care for the seriously injured patient no longer begins or ends in the emergency room. It is an increasingly complex, continuing process requiring the coordinated efforts of professionals in many fields. The University of North Carolina — North Carolina Memorial Hospital Statewide Trauma Center was established to provide such care. The proficiency of the Center extends to emergency medical services, acute care, transportation, communications, rehabilitation, research, epidemiology, education and highway safety engineering, areas neither possible nor economically reasonable in a small hospital. Thus, statewide centers must by definition be located in large hospitals.

Providing definitive care for individual victims of trauma is the sole function of the trauma service at Memorial Hospital. It is staffed by five general and thoracic surgeons. A chief resident, two assistant residents, medical students and surgeon's assistants are assigned to the service on a rotating basis. The staff is assisted by consultants from all the surgical disciplines and the departments of medicine, pediatrics and anesthesiology. The hospital's laboratories and radiological departments provide around-the-clock emergency support. Patients arriving at the hospital's Emergency Department are screened by the trauma team. Following stabilization and diagnosis, many patients are taken directly to surgery. The trauma service has priority access to an operating room equipped to permit measurements of such critical factors as cardiac output, pulmonary artery pressure, blood gases and pulmonary function. All patients with life-threatening injuries involving multiple organ systems are admitted to the 15-bed unit operated by the trauma service. The most critically injured and those voluntarily participating in research studies may be admitted to the Trauma Research Unit. Some patients who enter the trauma service are transferred to an appropriate specialty service after their conditions have been stabilized. There are in house at all times a fourth year surgical resident assisted by junior residents, with an attending surgeon in-house until midnight and all night on Saturday night. The Emergency Department is the physical link between the Trauma Center and the local and statewide Emergency Medical Service System. Radio communication permits physician supervision of emergency medical technicians serving in surrounding counties, as well as long-range communications with helicopters transporting patients to the hospital. Six physicians, three to five nurses and a variety of associated personnel are on duty in the Emergency Department at all times. Special areas are equipped to permit such complex resuscitation procedures as craniotomies and thoracotomies, in addition to the usual emergency services.

The North Carolina Jaycee Burn Center, a regional center for burn treatment, is located at Memorial Hospital. The 23-bed Burn Center offers the most advanced and effective methods of treatment for badly burned patients referred from hospitals throughout the state. The staff of the Burn Unit is experienced in dealing with the unique problems of resuscitation, recovery and rehabilitation presented by burn victims, and their efforts are supported by an aggressive program of burn injury research.

Critically injured patients who need the services of the trauma center may be flown to Memorial Hospital by helicopter. This service is provided by the Military Assistance

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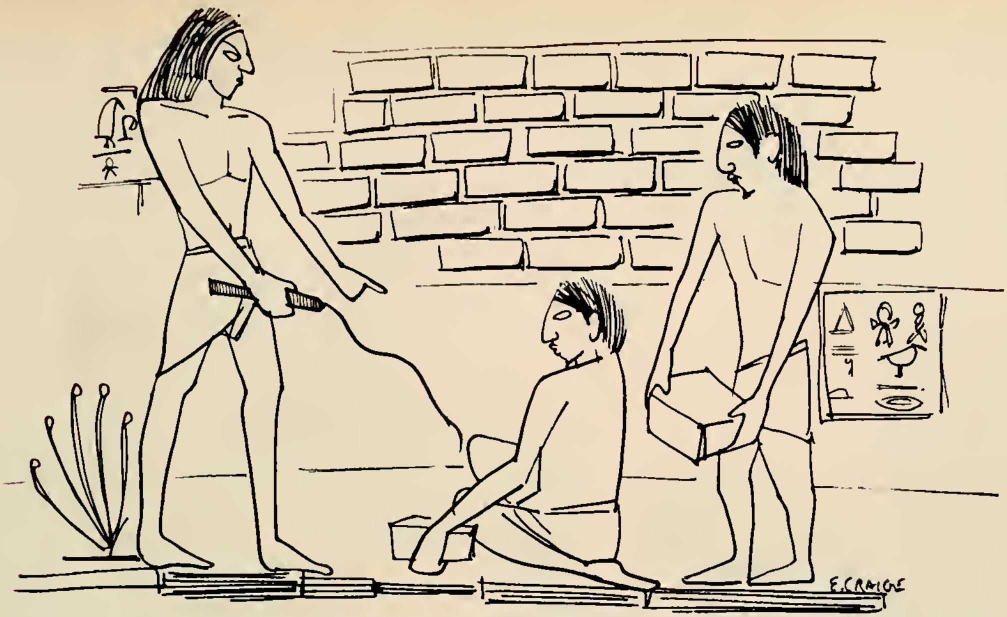
From the Trauma Section, Department of Surgery, University of North Carolina, Chapel Hill 27514.



to Safety and Traffic (MAST) program, a joint federal-state service. The civilian head of this program is located in Chapel Hill. The MAST Program utilizes Army helicopters and flight crews from Ft. Bragg. Together with Marine and Coast Guard rescue flights, the MAST program flies about 200 missions a year to Memorial Hospital, landing at the helistop near the hospital's Emergency Department.

The rehabilitation program at the statewide center helps patients achieve full recovery by offering an intensive plan of physical retraining, psycho-social counseling and vocational counseling. Physical and occupational therapy are frequently initiated in the acute phase of trauma care. A team of physical therapists evaluates each patient's needs and designs an appropriate treatment program to maintain and increase strength, mobility and coordination. Treatments may include hydrotherapy and electrotherapy, as well as exercise programs. Occupational therapists help the patient achieve maximum independence and productivity, both during and after the recovery process, through exercise and treatment programs. They also provide splinting and positioning devices that prevent joint deformity and loss of function.

Since a clear understanding of shock and improved care of traumatized patients will come as a result of scientific investigation, particularly at the cell level, the Laboratories of Shock and Cellular Metabolism were created as part of the trauma center. The laboratories operate the hospital's Trauma Research Unit as well as laboratories devoted to animal studies. Supported by grants from the National Institutes of Health and the military, the laboratories administer an annual research budget of about $200,000.

Almost 50 percent of admissions to the trauma service are related to highway accidents. The UNC Highway Safety Research Center, a component of the Statewide Center, was created to evaluate the state's existing highway safety programs, coordinate the training of persons involved in highway safety, and close the gap between knowledge gained through highway safety research and its use in saving lives. The activities of the Highway Safety Research Center include studies into highway engineering, motorcycle safety, driver improvement, school bus safety and law enforcement.

The Trauma Center staff conducts an extensive outreach program in addition to its educational activities within the medical center. Staff members regularly assist in the training of rescue squad personnel, and provide faculty for ATLS courses. An OEMS grant enables staff members to visit community hospitals for training sessions in resuscitation, transportation, and recognition of patients appropriate for referral.

Many of the costs associated with maintaining the above capabilities are fixed, and depending on how they are computed are variously estimated at two to three million dollars a year. It obviously makes sense, not only for patient care but to reduce the cost per patient, to concentrate them all in one statewide center, or in as few centers as geography and transportation systems permit. The negative effect of this philosophy is that it concentrates the entire economic burden on a few hospitals, penalizing those who, in a sincere desire to improve patient care, hold themselves out as trauma centers. The collection rate of the trauma service at the University of North Carolina — North Carolina Memorial Hospital Statewide Center is 40%! Although automobile liability insurance is mandatory in North Carolina, delay in settlement of claims creates a cash flow problem stretching into years, while there is no coverage for the average gunshot wound. The impact of DRGs on transfer patterns is yet to be felt.

Who then will pay to operate an organized statewide trauma care system? The answer is not altogether clear, but it is the author's opinion that, like fire and police protection, if the citizens of North Carolina want access to top flight trauma care, it should be part of the tax burden. Such a tax could be imposed on all at a few dollars per capita, or distributed among the high users of the system as a surcharge on license plates, drivers' licenses, gasoline, etc.

As mentioned in the introductory comments to this editorial, North Carolinians can be justly proud of the progress made in trauma care. The consequence, however, has been the creation of a system which runs the risk of economic sanctions against the very hospitals best equipped to provide care, asking them, as did Pharaoh, to make bricks without straw.

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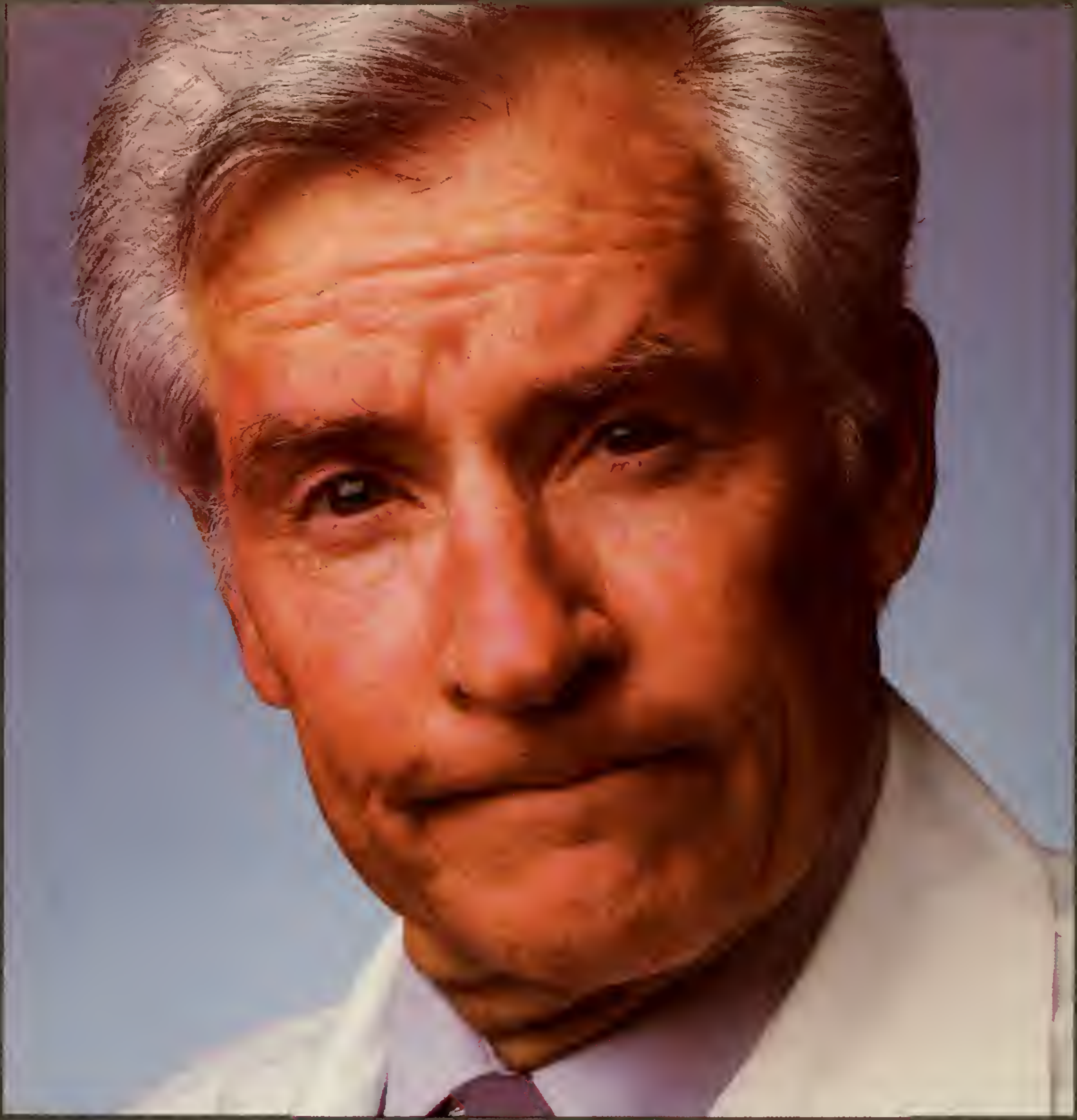
1. Proctor H J, Becker C, Gillings D: An analysis of the North Carolina Trauma/Burn Incidence and Severity Study. NCOEMS Report.



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TOXIC ENCOUNTERS

"To See a World In a Grain of Sand and a Heaven In a Wild Flower" — Oleander Poisoning

Ronald B. Mack, M.D.

• *The oleander – a fine plant to admire from afar.*

"HOLD Infinity In The Palm of Your Hand and Eternity In an Hour!!" These beautiful words of poetry you will immediately recognize as the opening lines of William Blake's *Auguries of Innocence*. Blake was the mystical English poet who died in 1827, not fully appreciated by the public for his artistic gifts (as none of us are). It is believed by some that he was the subtlest and most far reaching figure in the intellectual liberation of Europe that occurred at the end of the 18th Century.[1] (Leaping lizards, what does this have to do with toxicology?) In his references to innocence, he was thought to be talking about the imaginative separateness of the child. That is to say, his vision of innocence refers to the original state of happiness and spontaneous joy of childhood in which the imagination is totally free. This state can be achieved by adults as well.

Well, I am here to tell you that there is one "flower" that makes you "see heaven" in a hurry and it is the infamous *oleander*, AKA Nerium oleander. No question about it, this bit of flora is bad news; one leaf can kill an adult.

The oleander is a member of the dogbane family (that name dogbane should be a clue — plants in this family were used in the past to poison pesky, pesty, pets). This family contains in excess of 1,000 species of tropical trees, herbs, vines and shrubs and many of these species are very toxic, especially the Nerium oleander. In more remote historical times it was used as a protective substance to combat rodents and insects and was used as a remedy against malaria, leprosy, venereal disease (ouch!!), fever, as well as an abortifacient (watch your mouth, boy!!).

The oleander is quite pretty, but deadly, and is very popular as an ornamental shrub in our country's warmer climes: from Florida to California and in the Hawaiian Islands. In the more disagreeable, colder parts of the States it is grown as a house plant. How would you recognize this little darling without a name tag? I was reared in a concrete jungle and I couldn't identify it *with* a name tag. In any case, the shrub can be as tall as 20 feet. The leaves are unique and typically are a combination of simple, untoothed leaves produced in pairs. There is plenty of milky or gummy sap; the petals form a tube with a twisted appearance to the lobes. The fruit of the oleander is composed of one or two brown cigar or pencil shaped containers filled with myriads of small seeds.

The entire plant is potentially poisonous — the leaves, blossoms, twigs, sap, honey, seeds — all of it. This plant is so toxic — (how . . . toxic . . . is . . . it?) that if you put oleander in water, the water becomes poisonous; the smoke emanating from burning oleander is toxic; if you consume honey produced by bees who sucked the nectar from this fragrant evergreen you can be in big trouble, poison-wise. If you like to go camping, do not use an oleander branch as a meat or marshmallow skewer as you can die as a result of the toxin being transferred to the food. The oral lethal dose of oleander leaves in animals is approximately 0.5 mg per kilogram of body weight.

What does this plant contain that causes it to be so pernicious? The white and red flowering varieties contain at least five potent glycosides and at least 50 substances not yet identified. The major target organs of the toxins are the *cardiac* and *gastrointestinal* systems with death being caused by dysfunction of the heart. The cardiotoxic effects of oleander are probably due to the poisonous glycosides: *oleandrin, digitoxigenin* and *nerioside*. There are remarkable similarities in activity and chemical structure of these oleander glycosides and digitoxin (and of the foxglove plant). Many garden plants contain digitalis-like glycosides, e.g., the foxglove, of course, and lily of the valley and the star-of-Bethlehem. The oleander is thought to be more cardiotoxic than the foxglove.

If you happen to ingest oleander by accident or on purpose (it still is being used as a means of suicide) you immediately experience burning in the mouth — presumably due to the *saponins* in the plant. The saponins are quite irritating and are composed of various toxic surfactant glycosides. About one or two hours post ingestion the patient experiences *abdominal pain, nausea* and *vomiting, dizziness* and *bloody diarrhea* — an obviously miserable patient but hardly a specific syndrome. Later in the course of this devastating toxin (one to six hours) the patient experiences *bradycardia, drowsiness, loss of consciousness, hypotension, hypothermia, arrhythmias, dyspnea* and *death*. Morbidity and mortality seem to be related to the cardiotoxicity of the oleander plant's glycosides which produce the arrhythmias and heart block and hyperkalemia. The bradycardia often progresses to A-V block and asystole. The ventricular arrhythmias that can ensue include PVCs, tachycardia and fibrillation and then exit — "to see heaven in a wild flower."

Many authorities believe that the major cardiac effects of oleander result from direct cardiotoxic action as well as central effects via the vagus nerve. The digitoxin-like oleander glycosides inhibit the ATP-ase dependent cation pump of the heart muscle, similar to digitalis. This same pump inhibition probably produces the elevation of the serum potassium often seen in these patients. Cardiac abnormalities can last 48 hours.

Two of the most interesting clinical features of oleander poisoning relate to the eyes; there is marked *pupillary dilatation* and there is a *distinct visual perceptive change* experienced by the patient: yellow and green colors are seen by the patient as well as geometric patterns around objects. This calls to mind the fascinating paper concerning the Dutch postimpressionist artist Vincent Van Gogh.[2] During the last years of this artist's tragic life his paintings contained many objects surrounded by halos and many, many objects painted yellow. The author of this paper hypothesizes that the artist was ingesting digitalis. Why digitalis? Apparently in the later part of the 19th Century this drug was used to combat epilepsy from which Van Gogh allegedly suffered.

The management of the patient who ingested this very toxic plant should involve gastric decontamination if the patient is seen early enough. Oleander produces vomiting in many patients soon after ingestion and that of course is to the patient's distinct advantage. In conscious patients ipecac syrup is usually indicated, otherwise lavage is the way to go. Activated charcoal and a saline cathartic should then be administered to further complete the gastrointestinal decontamination. Some current experts recommend administering charcoal and a saline cathartic every four hours until a charcoal colored stool is passed (Good heavens!!) indicating proper GI cleansing. Apparently, in the laboratory, there is cross reactivity of digoxin antibodies between oleander glycosides and digoxin in the radioimmunoassay for digoxin. Therefore, in a patient in whom you suspect oleander ingestion a digoxin concentration may confirm your suspicions if no other digitalis source has entered the patient's body.

Definite treatment for oleander poisoning should be the same as for digitalis poisoning. This involves monitoring serum potassium levels and monitoring cardiac rhythms of course. You could use atropine for bradycardia, lidocaine or propranolol for ventricular tachycardia, phenytoin for ventricular arrhythmias and electrical pacing for heart block. It is urged that propranolol not be utilized if the patient is undergoing bradycardia or second or third degree heart block. Theoretically neither diuresis nor extracorporeal removal modalities should work. To my knowledge cardiac glycoside specific antibodies (Fab fragments of sheep digoxin-specific antibodies) have not been used yet in oleander poisoning but just maybe someone will try it.

"Greens" seem to be a stable element of the Southern diet. To be honest, I never liked them. Now I figure I have a good excuse — who knows — they could be feeding me oleander!! Take no chances!!

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Dr. Cannon died in 1966 at the age of 68. He will be long remembered—most especially by the more than 5000 North Carolinians he helped bring into the world, some of them at the side of a rutted country road.

Reference: 1. Doctor in the backwoods, in Lee RV, Eimerl S *et al* *The Physician* New York, Life Science Library, Time Inc, 1967, pp 38-50

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References: 1. Rickels K. Drug treatment of anxiety, in *Psychopharmacology in the Practice of Medicine,* edited by Jarvik ME, New York, Appleton-Century-Crofts, 1977, p 316 **2.** Feighner JP *et al: Psychopharmacology 61*:217-229, Mar 1979 **3.** Data on file, Hoffmann-La Roche Inc., Nutley, NJ

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> ***Usage in Pregnancy:*** **Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.**

Since physical and psychological dependence to chlordiazepoxide have been reported rarely, use caution in administering Limbitrol to addiction-prone individuals or those who might increase dosage, withdrawal symptoms following discontinuation of either component alone have been reported (nausea, headache and malaise for amitriptyline, symptoms [including convulsions] similar to those of barbiturate withdrawal for chlordiazepoxide).

Precautions: Use with caution in patients with a history of seizures, in hyperthyroid patients or those on thyroid medication, and in patients with impaired renal or hepatic function Because of the possibility of suicide in depressed patients, do not permit easy access to large quantities in these patients Periodic liver function tests and blood counts are recommended during prolonged treatment Amitriptyline component may block action of guanethidine or similar antihypertensives Concomitant use with other psychotropic drugs has not been evaluated, sedative effects may be additive Discontinue several days before surgery Limit concomitant administration of ECT to essential treatment See Warnings for precautions about pregnancy Limbitrol should not be taken during the nursing period Not recommended in children under 12 In the elderly and debilitated, limit to smallest effective dosage to preclude ataxia, oversedation, confusion or anticholinergic effects

Adverse Reactions: Most frequently reported are those associated with either component alone drowsiness, dry mouth, constipation, blurred vision, dizziness and bloating Less frequently occurring reactions include vivid dreams, impotence, tremor, confusion and nasal congestion Many depressive symptoms including anorexia, fatigue, weakness, restlessness and lethargy have been reported as side effects of both Limbitrol and amitriptyline Granulocytopenia, jaundice and hepatic dysfunction have been observed rarely

The following list includes adverse reactions not reported with Limbitrol but requiring consideration because they have been reported with one or both components or closely related drugs

Cardiovascular Hypotension, hypertension, tachycardia, palpitations, myocardial infarction, arrhythmias, heart block, stroke

Psychiatric: Euphoria, apprehension, poor concentration, delusions, hallucinations, hypomania and increased or decreased libido

Neurologic: Incoordination, ataxia, numbness, tingling and paresthesias of the extremities, extrapyramidal symptoms, syncope, changes in EEG patterns

Anticholinergic Disturbance of accommodation, paralytic ileus, urinary retention, dilatation of urinary tract.

Allergic Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus

Hematologic: Bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia

Gastrointestinal: Nausea, epigastric distress, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, black tongue

Endocrine Testicular swelling and gynecomastia in the male, breast enlargement, galactorrhea and minor menstrual irregularities in the female, elevation and lowering of blood sugar levels, and syndrome of inappropriate ADH (antidiuretic hormone) secretion

Other: Headache, weight gain or loss, increased perspiration, urinary frequency, mydriasis, jaundice, alopecia, parotid swelling

Overdosage: Immediately hospitalize patient suspected of having taken an overdose Treatment is symptomatic and supportive I V administration of 1 to 3 mg physostigmine salicylate has been reported to reverse the symptoms of amitriptyline poisoning See complete product information for manifestation and treatment

Dosage: Individualize according to symptom severity and patient response Reduce to smallest effective dosage when satisfactory response is obtained Larger portion of daily dose may be taken at bedtime Single *h.s* dose may suffice for some patients Lower dosages are recommended for the elderly

Limbitrol 10-25, initial dosage of three or four tablets daily in divided doses, increased up to six tablets or decreased to two tablets daily as required Limbitrol 5-12 5, initial dosage of three or four tablets daily in divided doses, for patients who do not tolerate higher doses

How Supplied: White, film-coated tablets, each containing 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt) and blue, film-coated tablets, each containing 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt)—bottles of 100 and 500, Tel-E-Dose® packages of 100, Prescription Paks of 50

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LEARNING WITHOUT WORDS

Source of Hair in a Pilonidal Sinus

Louis deS. Shaffner, M.D.

• *Where the hair comes from, how to treat the abscess and how to prevent a recurrence.*

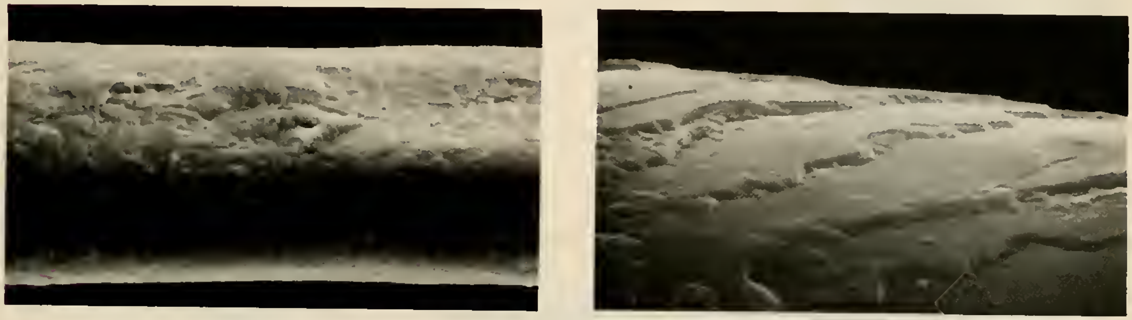

Figure 1: *Scanning electron microscopy of body hair shaft (left 520 × ; right 5200 ×). Root end is to the left.*

THE authors of recent articles on acute pilonidal sinus disease agree that it is an acquired infection secondary to hair in a pre-existing or *de novo* sinus in the intergluteal fold. There is still disagreement on how hair gets there. Current surgical textbooks postulate the "ingrowth" of hair; Raffman[1] suggests "implantion" by friction. Most authors agree that the hairs are always loose, and that they always lie with the root ends deep in the sinus. It is generally accepted that the sinuses do not contain hair follicles.

The scales on the hair shaft are like overlapping shingles from the root toward the tip (figure 1). Patey and Scarff[2] have postulated and Page[3] has demonstrated that the orientation of the scales is such that friction on the shaft between two skin surfaces, such as the nates, will cause the hair to migrate in the direction of the root end. This migration can be easily demonstrated by rubbing a hair longitudinally between the thumb and finger (figure 2). By that mechanism shed hairs can enter a pilonidal sinus.

In acute pilonidal sinus infection the abscess usually points to one side, but there is always at least one sinus opening in the midline (figure 3). It is through that opening that infection can start and hair shafts can migrate.

Adequate treatment, therefore, requires not only drainage of the abscess cavity, but also the removal of all midline pits or sinuses.[4] In an early case with only a small abscess,

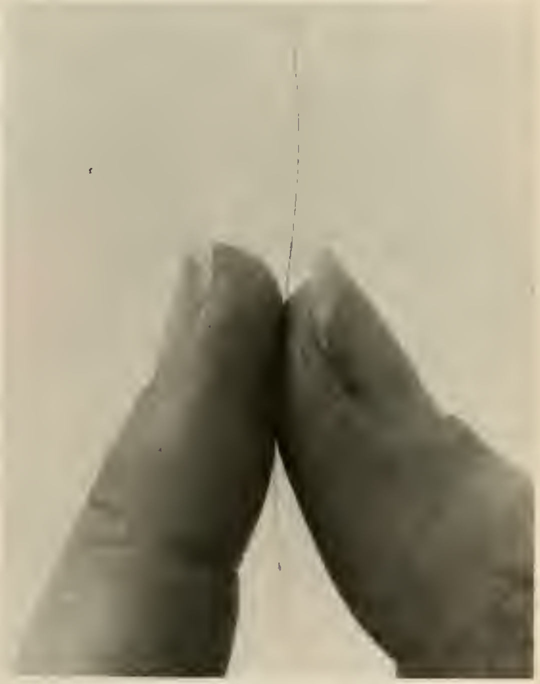

Figure 2: *Stroking a hair longitudinally with thumb and finger will cause it to migrate toward the root end.*

From the Department of Surgery, Bowman Gray School of Medicine of Wake Forest University, Winston-Salem 27103.

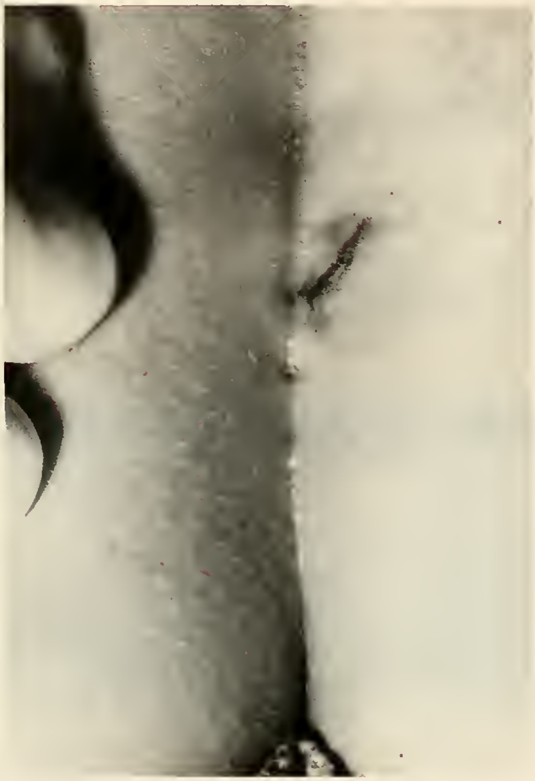

Figure 3: *Persistent midline pilonidal sinuses with recurrent infection after healing of previously drained abscess.*

this can all be done at one time under local anesthesia without hospital admission. Wide excisions of skin and the abscess wall are not necessary, but open packing for secondary healing is required. This could have been done in the case illustrated, thus obviating a second procedure.

Early skin bridging is prevented by weekly office treatments, and the hair is shaved as necessary until healing is complete in 4 to 6 weeks. After that the patient daily can remove loose hairs by stroking the area with the sticky side of a strip of adhesive tape folded over the finger tips.

For a patient with early irritation and visible hair shafts protruding from a small sinus, manual removal of the hair, sitz baths, and the daily use of adhesive tape may well forestall the development of an acute abscess.

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3. Page BH. The entry of hair into a pilonidal sinus. Br J Surg 1969;56:32.
4. Hanley PH. Acute pilonidal abscess. Surg Gynecol Obstet 1980;150:9-11.

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DESCRIPTION
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INDICATIONS.
Adjunct in short-term treatment of pain accompanied by tension and/or anxiety in patients with musculoskeletal disease Clinical trials demonstrated that in these situations relief of pain is somewhat greater than with aspirin alone Effectiveness in long-term use, i e over 4 months, has not been assessed by systematic clinical studies Physicians should periodically reassess usefulness of drug for individual patients

CONTRAINDICATIONS
ASPIRIN Allergic or idiosyncratic reactions to aspirin or related compounds

MEPROBAMATE Acute intermittent porphyria allergic or idiosyncratic reactions to meprobamate or related compounds e g carisoprodol, mebutamate or carbromal

WARNINGS
ASPIRIN Use salicylates with extreme caution in patients with peptic ulcer asthma coagulation abnormalities, hypoprothrombinemia vitamin K deficiency, or those on anticoagulants In rare instances, aspirin in persons allergic to salicylates may result in life-threatening allergic episodes

MEPROBAMATE DRUG DEPENDENCE
Physical and psychological dependence and abuse have occurred Chronic intoxication from prolonged ingestion of usually greater than recommended doses is manifested by ataxia, slurred speech, and vertigo Therefore, carefully supervise dose and amounts prescribed and avoid prolonged use, especially in alcoholics and others with known propensity for taking excessive quantities of drugs Sudden withdrawal after prolonged and excessive use may precipitate recurrence of preexisting symptoms, e g anxiety, anorexia, or insomnia or withdrawal reactions e g , vomiting, ataxia, tremors, muscle twitching, confusional states, hallucinosis and, rarely, convulsive seizures Such seizures are more likely in persons with CNS damage or preexistent or latent convulsive disorders Onset of withdrawal symptoms occurs usually within 12 to 48 hours after discontinuation symptoms usually cease within next 12- to 48 hour period When excessive dosage has continued for weeks or months reduce dosage gradually over 1 to 2 weeks rather than stop abruptly Alternatively a short-acting barbiturate may be substituted then gradually withdrawn

POTENTIALLY HAZARDOUS TASKS Warn patients meprobamate may impair mental or physical abilities required for potentially hazardous tasks e g driving or operating machinery

ADDITIVE EFFECTS Since CNS-suppressant effects of meprobamate and alcohol or meprobamate and other psychotropic drugs may be additive, exercise caution with patients taking more than one of these agents simultaneously

USAGE IN PREGNANCY AND LACTATION:
An increased risk of congenital malformations associated with minor tranquilizers (meprobamate, chlordiazepoxide, and diazepam) during first trimester of pregnancy, has been suggested in several studies Because use of these drugs is rarely a matter of urgency, their use during this period should almost always be avoided. The possibility that a woman of childbearing potential may be pregnant at time of institution of therapy should be considered Advise patients if they become pregnant during therapy or intend to become pregnant to communicate with their physicians about desirability of discontinuing the drug

Meprobamate passes the placental barrier It is present both in umbilical-cord blood at or near maternal plasma levels and in breast milk of lactating mothers at concentrations two to four times that of maternal plasma When use of meprobamate is contemplated in breastfeeding patients, consider the drug s higher concentrations in breast milk as compared to maternal plasma levels

USAGE IN CHILDREN Keep preparations with aspirin out of reach of children Equagesic® (meprobamate with aspirin) is not recommended for patients 12 years of age and under

PRECAUTIONS
ASPIRIN Salicylates antagonize uricosuric activity of probenecid and sulfinpyrazone Salicylates are reported to enhance hypoglycemic effect of sulfonylurea antidiabetics

MEPROBAMATE Use lowest effective dose particularly in elderly and/or debilitated, to preclude over-sedation Meprobamate is metabolized in the liver and excreted by the kidney to avoid excess accumulation exercise caution in its use in patients with compromised liver or kidney function Meprobamate occasionally may precipitate seizures in epileptic patients It should be prescribed cautiously and in small quantities to patients with suicidal tendencies

ADVERSE REACTIONS:
ASPIRIN May cause epigastric discomfort, nausea and vomiting Hypersensitivity reactions, including urticaria, angioneurotic edema purpura asthma and anaphylaxis may rarely occur Patients receiving large doses of salicylates may develop tinnitus

MEPROBAMATE CNS Drowsiness, ataxia dizziness, slurred speech, headache vertigo, weakness paresthesias, impairment of visual accommodation, euphoria overstimulation paraodxical excitement, fast EEG activity

GI Nausea vomiting, diarrhea

CARDIOVASCULAR Palpitation, tachycardia various forms of arrhythmia, transient ECG changes, syncope, hypotensive crisis

ALLERGIC OR IDIOSYNCRATIC Milder reactions are characterized by itchy, urticarial, or erythematous maculopapular rash, generalized or confined to the groin Other reactions include leukopenia acute nonthrombocytopenic purpura, petechiae, ecchymoses eosinophilia, peripheral edema, adenopathy fever fixed drug eruption with cross-reaction to carisoprodol, and cross-sensitivity between meprobamate/mebutamate and meprobamate/carbromal Rare more severe hypersensitivity reactions include hyperpyrexia, chills angioneurotic edema bronchospasm, oliguria, and anuria Also, anaphylaxis, exfoliative dermatitis, stomatitis, and proctitis Stevens-Johnson syndrome and bullous dermatitis have occurred

HEMATOLOGIC (SEE ALSO "ALLERGIC OR IDIOSYNCRATIC") Agranulocytosis aplastic anemia have been reported although no causal relationship has been established and thrombocytopenic purpura

OTHER Exacerbation of porphyric symptoms

DOSAGE AND ADMINISTRATION
Usual dose is one or two tablets, 3 to 4 times daily as needed for relief of pain when tension or anxiety is present Not recommended for patients 12 years of age and under

OVERDOSAGE
Treatment is essentially symptomatic and supportive Any drug remaining in the stomach should be removed Induction of vomiting or gastric lavage may be indicated Activated charcoal may reduce absorption of both aspirin and meprobamate Aspirin overdosage produces usual symptoms and signs of salicylate intoxication Observation and treatment should include management of hyperthermia, specific parenteral electrolyte therapy for ketoacidosis and dehydration, watching for evidence of hemorrhagic manifestations due to hypoprothrombinemia which, if it occurs, usually requires whole-blood transfusions Suicidal attempts with meprobamate have resulted in drowsiness, lethargy, stupor, ataxia coma shock vasomotor and respiratory collapse Some suicidal attempts have been fatal The following data reported in the literature and from other sources are not expected to correlate with each case (considering factors such as individual susceptibility and length of time from ingestion to treatment) but represent usual ranges reported Acute simple overdose (meprobamate alone) Death has been reported with ingestion of as little as 12 grams meprobamate and survival with as much as 40 grams

BLOOD LEVELS
0 5-2 0 mg percent represents usual blood level range of meprobamate after therapeutic doses The level may occasionally be as high as 3 0 mg percent

3-10 mg percent usually corresponds to findings of mild-to-moderate symptoms of overdosage, such as stupor or light coma

10-20 mg percent usually corresponds to deeper coma requiring more intensive treatment Some fatalities occur

At levels greater than 20 mg percent, more fatalities than survivals can be expected

Acute combined overdose (meprobamate with other psychotropic drugs or alcohol) Since effects can be additive, history of ingestion of a low dose of meprobamate plus any of these compounds (or of a relatively low blood or tissue level) cannot be used as a prognostic indicator

In cases of excessive doses sleep ensues rapidly and blood pressure pulse and respiratory rates are reduced to basal levels Any drug remaining in stomach should be removed and symptomatic treatment given Should respiration or blood pressure become compromised respiratory assistance CNS stimulants and pressor agents should be administered cautiously as indicated Diuresis osmotic (mannitol) diuresis, peritoneal dialysis, and hemodialysis have been used successfully in removing both aspirin and meprobamate Alkalinization of the urine increases excretion of salicylates Careful monitoring of urinary output is necessary, and caution should be taken to avoid overhydration Relapse and death, after initial recovery have been attributed to incomplete gastric emptying and delayed absorption

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PHARMACOTHERAPY

Clinical Uses of Anti-Thymocyte Globulin (ATGAM), Part I

Colleen Gilbert

• The first part of a two-part article on using ATG in immune-mediated diseases.

ANTI-THYMOCYTE globulin (ATG) is an immunosuppressive agent of value in clinical renal transplantation and other investigational uses. It is commercially available from Upjohn as ATGAM sterile solution and has been approved for use in the management of renal allograft rejection since 1981.[1, 2] This agent is used for its lymphocyte-selective immunosuppressive actions in an array of immune-mediated disease states. ATG has been examined for use in organ transplantation rejection therapy,[3-14] aplastic anemia,[15-21] lymphomas and leukemias,[22, 23] graft-versus-host disease,[24-26] multiple sclerosis[27] and myasthenia gravis.[28, 29] The use of ATGAM remains controversial despite the established clinical benefits for some patients. In addition to ATGAM, there are other, non-FDA approved anti-lymphocyte globulin preparations available around the country. In particular, there have been extensive studies with an anti-sera produced at the University of Minnesota called Minnesota Anti-lymphoblast Globulin (MAG).[1, 30] In order to avoid confusion, the following discussion will be limited to clinical trials of ATGAM unless otherwise indicated.

Immunopharmacology

ATG is an equine, heterologous antibody prepared against human thymocytes.[2] This purified globulin is a potent immunosuppressive agent in animal models.[1] Therapeutic efficacy of ATG in humans has been controversial. The precise mechanism of its action is not yet known. A brief review of immunoglobulin structure and function, and of the human immune system, will aid in the understanding of ATG function, including adverse effects.[31, 32]

A schematic drawing of a monomeric IgG immunoglobulin is seen in figure 1. The Fab portion of the molecule binds to specific antigenic sites to form antigen-antibody complexes. These complexes may activate the complement cascade to cause complement-mediated cytotoxicity or they may be subsequently phagocytosed by macrophages or polymorphonuclear neutrophils. The Fc portion of the molecule is responsible for various biological activities of the antibody such as complement activation and the ability to cross the placenta. Many sub-populations of cells, such as B-cells, carry Fc-receptors on their surface which bind immunoglobulin and mediate further immune responses. The immune system consists of the integrated actions of T and B lymphocytes and macrophages. There are two functional components to the human immune system: cell-mediated immunity and humoral immunity. The cellular axis consists of T cells, macrophages and soluble lymphokines. Cellular immunity is activated by T-cell recognition of antigen. This results in release of various lymphokines and activation of macrophages. The macrophage is important in presentation of antigen to T and B cells as well as for its action as an effector cell to phagocytose foreign material. A subpopulation of T cells can be stimulated to proliferate and directly kill foreign cells. These effector T-cytotoxic cells are regulated by two other types of T cells known as suppressor and helper T cells. Helper T cells act as inducer cells to mediate both cellular and humoral immune response. They release soluble lymphokines such as T cell growth factor (TCGF). Suppressor T cells exist in a relatively fixed ratio to helper T cells and are important in the fine tuning of humoral and cell-mediated immune responses. The humoral axis of the immune system is re-

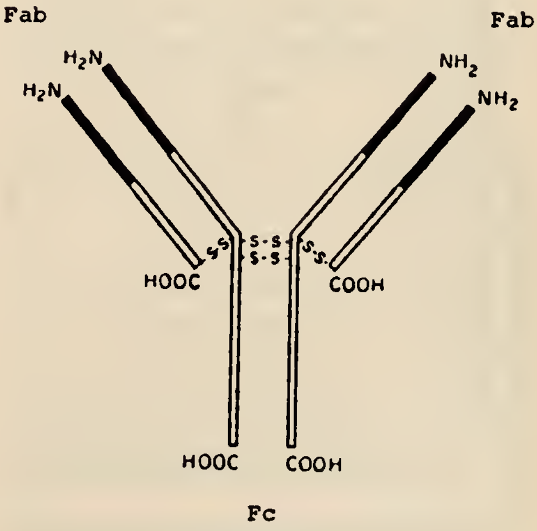

Figure 1.

From the Department of Pharmacy, Duke University Medical Center, Durham 27710.

sponsible for the production of antibody and is particularly essential to fight pyrogenic bacterial infections. The B cell has immunoglobulin as well as Fc receptors on its surface membrane. Antigens may directly bind the cell and stimulate immunoglobulin production (T-independent antibody) or T helper cells and macrophages may augment B cell response by antigen presentation (T-dependent antibody). Generally, foreign serum proteins are thymus dependent immunogens. Upon initial antigenic challenge, the B cells respond with a low titer of T-independent IgM antibody which appears in approximately ten days. Rechallenge of the humoral immunity results in a much higher titer of IgG antibody which is T-dependent and appears in three to five days. Continued boosting of the immune system by multiple exposure to antigen may result in a hyperimmune serum with high concentrations of IgG antibody. This is an important principle behind the production of anti-thymocyte globulin.

ATGAM is produced by immunizing horses with thymocytes obtained from thymus tissue removed during surgery.[33] Other sources of antigen which can be used are peripheral blood lymphocytes, lymphoblastoid cell lines and cadaveric splenic lymphocytes.[31] Species which may be used to prepare anti-lymphocyte sera include goat, rabbit and horse.[28, 31] ATGAM is prepared in horses due to the large volumes of plasma that can be obtained. The horses are injected with purified thymocytes every two weeks for three months. Equine plasma is drawn into sterile, heparinized bottles biweekly. The pooled equine plasma is then processed and purified monomeric IgG is isolated. This is then absorbed with human erythrocyte stroma and soluble human plasma proteins to remove cross-reactive antibodies to these substances. The final yield is 9-16 grams IgG protein per liter of plasma.[33]

There are many *in vitro* and *in vivo* assays used to assess the safety and potency of each ATG lot.[33] The rosette inhibition assay is used to qualitatively predict ATG potency. A titer of ≥ 1:5,000 is considered desirable. A T cell rosette is formed by the binding of sheep red blood cells to thymocyte surface membrane. Inhibition of rosetting indicates functional T cell damage by the ATG. Inhibition of T cell rosetting generally correlates with increased graft survival time in the Monkey Skin Graft Survival Assay.[33, 34] The skin grafts survive seven to 10 days without ATG and may be prolonged to over 30 days with ATG. However, clinical efficacy has not been proven to correlate with these assays. Reports have been conflicting and ATG lot variability remains a major concern with the use of ATGAM.

The precise mechanism of action of ATG has not been elucidated. In general, the immunosuppressive effect of ATG is due to binding to T cells and inhibition of good cell mediated immune response.[1, 2] A recent study by Thomas et al indicates that effective ATG is correlated with enhancement of non-specific suppressor cells.[34] Binding of T cells by ATG may cause actual thymocyte destruction by complement-mediated cytotoxicity or macrophage activation and phagocytosis. Alternatively, the ATG may inhibit cell membrane changes necessary for cytotoxic T cell activity or may neutralize lymphokines produced by the T cell. In any case, anti-thymocyte globulin clearly acts on the cell-mediated immune system and has minimal effect on the humoral immunity.

In clinical transplantation, the HLA/DR histocompatability antigens are responsible for organ rejection phenomena.[31, 32] The host recipient recognizes foreign surface antigens on the donor organ and mounts both a cell-mediated and a humoral immune response. Cytotoxic T effector cells are primarily responsible for acute cellular rejection episodes, and antibodies are responsible for acute humoral rejection. If donor and recipient are perfect HLA matches, as in identical twins, the allograft is much more likely to survive. Unfortunately, such perfect matches are rare and HLA antigen mediated rejection is a major problem in clinical transplantation. The presence of HLA-D/Dr sensitizing antigen causes stimulation of helper T cells. Proliferation of the helper cells can result in direct binding and lysis of HLA/Dr antigen bearing cells. In addition, these T helper cells amplify cytotoxic T cell response to the other HLA-A,B,C antigens and mediate B-cell production of antibodies to the incompatible HLA antigen bearing cells. ATG may act in this setting to bind T cells and inhibit helper and cytotoxic T cell function.[31] It may also prevent the production of soluble mediators by helper T cells and decrease the stimulatory effect of HLA-D/Dr antigens.[31]

Renal Allograft Rejection

Allograft rejection has historically been controlled by immunosuppressive therapy with azathioprine and corticosteroids. The azathioprine dose (3-5 mg/kg/day) is adjusted according to complete blood counts and steroid doses are tapered over weeks to months. This approach has resulted in approximately 50% graft survival at one year for cadaveric renal allografts.[31] Onset of acute rejection episodes is seen at 7 to 21 days post-transplantation. Symptoms include fever, chills, oliguria, and a swollen, tender graft.[31] ATGAM is approved for use in renal allograft recipients for the prevention and treatment of acute rejection episodes. Studies generally have looked at the effect of adding ATG to the current immunosuppressive regimen. These studies are difficult to evaluate and compare, due to ATGAM lot variability, poorly selected controls and dosage variability.[1]

A prospective, randomized trial of prophylactic ATG therapy in cadaveric renal allograft recipients was reported by Cosimi in 1981.[35] Control patients ($n = 44$) received standard azathioprine and corticosteroid immunosuppressive therapy, while the ATG study group ($n = 60$) received this regimen plus 14 days of ATGAM (10-30 mg/kg/day). Those patients receiving concomitant ATG experienced significantly fewer rejection episodes in the first 60 days after transplantation (56% vs 84%; $p<0.05$). There were equal numbers of serious infections in all patients and fewer cases of avascular necrosis of the bone in the ATG group. This may have been due to decreased steroid requirements in those patients.

Kountz et al looked at ATG dosage and graft survival in cadaveric renal transplantation.[6] Control patients ($n = 21$) received azathioprine (150 mg/day) and prednisone, low dose ATGAM patients ($n = 30$) received additional ATG-250 mg QD for 14 days, and high dose ATGAM patients ($n = 22$) received ATG 750 mg QD for 14 days. They found no benefit to using low dose ATG but noted significant improvement in renal graft survival in patients receiving high dose ATG ($p<0.03$). Those patients showed delayed onset of first rejection episodes, lower total steroid dose and increased percentage of functional graft survival rates at 12 months.

In another multicenter trial of a 14 dose ATG regimen, four different ATGAM lots were compared.[12] Wechter et al evaluated a total of 360 patients. All patients received standard immunosuppression with azathioprine and prednisone. Both living related and cadaveric renal allografts were included in the study. Those patients receiving additional ATG therapy were given an average dose of 20 mg/kg/day for 14 days. Results were variable, with only one of four ATGAM lots demonstrating significantly fewer rejection episodes in the first 28 days post-transplantation ($p \leq 0.01$). Graft survival at 12 months slightly favored ATG but was not statistically significant for three of the lots. They also noted that steroid requirements were not significantly decreased at 28 days by the use of ATGAM. The rosette inhibition and monkey skin graft survival assays did not predict clinical efficacy of ATGAM lots in this trial.

Wechter et al went on to look at extended treatment with ATG in 20 cadaveric renal allograft patients.[13] These patients received azathioprine, prednisone plus ATGAM as follows; 7 mg/kg/day × 4 days, 3.5 mg/kg/day × 26 days, 7 mg/kg twice weekly × 8 weeks, and finally, 7 mg/kg once a week for the last 4 weeks. Control patients ($n = 20$) received the azathioprine and prednisone alone. Results of this regimen were much more encouraging. There were significantly fewer rejection episodes in the first 14 (25% vs 65%; $p<0.03$) and 28 (45% vs 85%; $p<0.02$) days and functional graft survival at 12 months (70% vs 35%) and 24 months (60% vs 35%) was improved in the ATG study group. ATGAM has been evaluated in several studies for reversal of established renal allograft rejection. Shield et al reported a prospective, randomized study of ATG in the treatment of rejection in recipients of living related donor renal allografts.[9] Patients were treated prophylactically with azathioprine and prednisone. When acute rejection episodes were documented patients were randomized to receive either ATG 15 mg/kg/day for 14 days then QOD for 14 days, or 1 g/day Solu-Medrol for 5 days followed by an oral prednisone taper. Results showed that ATG reversed rejection twice as fast as steroid therapy (3.1 vs 6.3 days). Although allograft survival was identical in the two groups, patients receiving ATG required significantly less total steroids in the first 60 days post-transplantation.

A similar study by Nowygrod et al compared ATGAM (15 mg/kg/day × 10 or 12 days) with methylprednisolone (15 mg/kg × 4 days then tapered) for reversal of renal allograft rejection.[8] Both regimens were essentially equivalent for treatment of rejection. However, the grafts lost in the ATG group (5/32) were documented (by biopsy) to be due to humoral rejection. They also noted improved allograft survival at 12 months and decreased mortality rate in patients receiving ATG. An important point of this study is that patients receiving the 10 day ATG regimen had more frequent second rejection episodes than those patients treated for 14-21 days.

Filo et al also evaluated therapy of acute renal allograft rejection with ATG.[16, 17] ATGAM (10 mg/kg × 15 days) was randomized versus methylprednisolone (30 day taper) to treat all rejection episodes in 79 patients who had received cadaveric or LRD kidneys. Patients receiving ATGAM for a first rejection episode responded more rapidly than patients treated with steroids ($p = .05$) and percent graft survival was higher with ATG ($p = .02$). However, subsequent rejection episodes treated with ATG or steroids reversed in an equal number of days and percent graft survival was also equal. Accumulated graft survival after three rejection episodes was better in the ATG groups, particularly in those LRD allograft recipients (79% vs 59%).

Part II will appear in the December 1984 issue of the NCMJ.
References available from the NCMJ editorial office.

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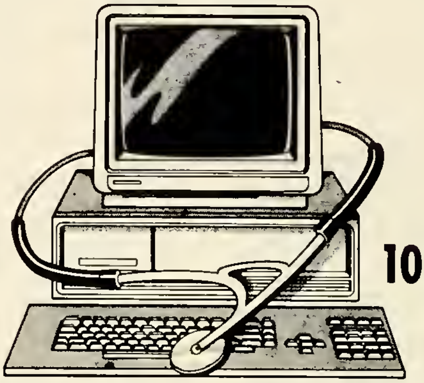

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Overlap Between Public Health and Private Physician

Eugene W. Linfors, M.D., editor

The question for November is: **What areas of the public health sector overlap with those of the personal physician? What areas should overlap?**

From Dr. Robert G. Brame, an obstetrician and gynecologist in Raleigh.

Public health departments provide health maintenance, prenatal care, contraception and diagnosis and treatment of sexually transmitted diseases to a segment of the population who do not have the financial resources to see a private, ''personal'' physician, although a small percentage of patients who take advantage of health department services are not medically indigent. The health department, for the most part, however, provides services to the indigent and until some other way to provide that service is devised, health departments will likely continue to serve as ''primary physician'' to many of our citizens.

From Dr. W. B. Bunn, an occupational medicine specialist in Durham.

Perhaps the only significant addition to the Hippocrates historical evaluation was added by Ramazzini in 1713. He stated, ''when a doctor visits a working class home he should be content to sit on the three legged stool if there isn't a gilded chair and he should take time for his examination.'' To the questions recommended by Hippocrates add one more — What is your occupation?

Although it is estimated that at least 20% of all cancer cases are occupationally related and 3.2 million workers are disabled and 60.5 workdays are lost per one hundred workers, the occupational history is commonly missing from charts of both outpatients and inpatients. In a technological society where there are hundreds of thousands of chemical compounds used in industry, the toxic and carcinogenic effects of chemicals must be considered. Therefore it has become important that an occupational or environmental etiology be considered for all disease processes.

For example, in consultation I recently saw a patient with a peripheral neuropathy who had been evaluated by a general practitioner, an internist, and a neurologist. Although two of the physicians had asked the occupation of the patient and several possible exposures has been elicited, no formal occupational history had been taken. In this particular case the patient was manager of a print shop and had minimal exposure to chemicals in the usual course of employment. He had, however, recently misapplied a herbicide to weeds around his workplace without protective equipment. The onset of the disease process and the degree of exposure were consistent with an acute toxic neuropathy which was documented by clinical testing. The patient was withdrawn from further exposure and he regained full function.

Health care personnel often omit the occupational history because the exposures are unfamiliar to them or are regulated by occupational or environmental standards. The former is not acceptable practice and the latter assumption is not a valid one since only a small percentage of the hundreds of thousands of chemicals are regulated and most chemicals have not been tested for adverse effects. In addition, it is impossible to enforce governmental standards given the resources available.

Further, physicians often decide that a detailed occupational history and definition of an exact agent are unnecessary since the patient may have ceased exposure or can be withdrawn from exposure. This decision creates two problems. First, other workers are commonly exposed to the agent and may have a similar adverse effect. Prevention is the best solution for all disease processes and the reduction of occupational exposure to harmful agents is an excellent example. Second, the definition and clarification of the exposure will aid in determining the prognosis of the acute process and future risks. It may also allay the financial burden of treatment by alternate compensation systems designed for this purpose.

In conclusion, omission of the occupational health history from the history and physical works to the detriment of the patient and society. It is an important tool in patient care, preventive medicine, and assessment of future risks and responsibilities.

From Dr. Jesse B. Caldwell, Jr., a gynecologist in Gastonia.

One *could* ask, ''what areas of a personal physician overlap with those of public health?,'' since there seems to be evidence that public health came first. Recorded history indicates that quarantine and isolation were used in the time of Moses and Aaron in cases of leprosy. The Romans built sewers and baths to control disease.

In times since, public health services have encompassed wider areas of medicine. These have accelerated since the isolation of the tubercle bacillus just over a hundred years ago and the acceptance of the "germ theory of disease."

Today, the two sectors do overlap in many areas. While enumeration and identification would be interesting, it appears that such overlapping is a balancing act and not necessarily a competitive one even though some public health facilities are now charging for services such as immunizations, pap smears, etc.

Areas that should overlap would be those services which could be provided by a public health department to persons of limited means who would not otherwise use a personal physician. Also, instances are known when a patient with a condition, such as a venereal disease, prefers to visit a public health facility.

There seems to be little interest by physicians in the overlapping in areas of environmental health services, such as sanitary control of water supplies, sewage disposal, regulation of food distribution, and also the collection of vital statistics, etc.

From Dr. Martin J. Kreshon, an ophthalmologist from Charlotte.

Over the past twenty-three years I have been actively involved in the private practice of ophthalmology in the largest city in the Carolinas. In dealing with a very busy practice, I have found that there is an unquenchable thirst for medical knowledge existing in most of my patients. There has been a "communication gap" between the patient and his physician. All of us who have been blessed with the title "physician" need to be aware of these needs and make some attempt to communicate our knowledge to our patients.

Most of us have had some experience in giving informative medical talks at the PTA, industrial safety conferences, civic club luncheons or talk shows at the local radio or TV station. When an audience is asked to "open up" we are all amazed by the depth and number of intelligent questions posed for the physicians. Such exchanges can act as a two-way street reaping rewards to both participants.

Such is the case in the eye donor arena. Audiences want to know more about donation of eyes and having obtained this information, they are in a much better position to decide concerning a donor card. In approaching a family for possible donation of corneal tissue, I have found that knowledge concerning transplantation or a contact with a local Lions Club member who had discussed possible eye donor situations, has always been helpful in coming to some agreement concerning the use of the tissue. The "public sector" attitudes can be a tremendous help to any of us who find a need for communication which must be accomplished in a short period of time. Time spent in informative service to others will reap benefits for all types of physician-public relationships in the future.

From Dr. Nicholas E. Stratas, a psychiatrist in Raleigh

To speak of overlap is in some quarters touted as good, but it appears that a more pluralistic system may emphasize care for the middle class and continue to abandon the indigent. Mental health center (and proprietary system) proponents argue that a locally based and free market should improve mental health care. There is nothing in the research literature to explore how types of terms of patient-physician-institution contracts affect efficacy and quality of care or type of patients served. It seems clear that method of payment (fee-for-service, prepayment, public payment) will affect the contract and, therefore, the service delivery. Public mental health hospitalization (and lump sum prepayments) encourage staff to extend length of hospital stay. In addition, accountability, which is quite clear in the patient-physician relationship of the personal physician, is unclear in the public (and often in proprietary) systems and can be expected to produce economic and patient abuse. Nonprofit systems are five to seven times more likely to deliver unreimbursed or underreimbursed services than are private for-profit providers.

There are clearly overlapping inpatient systems of care — the state funded public state hospitals and mental health centers, the for-profit hospital chains and psychiatric units in general hospitals. There is also overlapping in the provision of outpatient services — the public mental health state/local government funded and the personal physician provided. Except for academic settings, the for-profit chains have not yet moved into outpatient services in North Carolina. Whether and what areas should overlap is a moot question. The quality of our system of care is predicated on the personal physician-patient contract. This model needs to be an integral part of any other system. The public mental health system should shift to a private sector, personal physician model and recognize its "third party" role in services for the indigent population with the population able to pay personally or through other third party coverage given the option to choose. Even in the institutional settings, public mental health and proprietary, the basic model needs to be the personal physician-patient contract. This needs to be established at first contact and stated clearly to include goals, initially evaluatory and diagnostic, then treatment planning integrating the patient goals, identifying the treatment modalities, the temporal needs and the cost and mode of payment. Public mental health facilities should explore the open staff, personal physician model. Public mental health services can provide medical assessment and care for the chronically mentally ill, with each patient having a personal physician responsible for his or her care. The public mental health system can provide the rehabilitative, socialization and domiciliary supports whether in a state hospital or local mental health setting.

The chronically mentally ill are extremely vulnerable as consumers of care because they frequently cannot make informed decisions. State government then becomes the actual consumer of care and should intercede for the chronic mentally ill, promote public information programs and foster personal physician involvement as service providers. A further problem with the chronic mentally ill is that only 10 percent live with their families, 15 percent in state mental hospitals and 68 percent in nursing or boarding homes. Here as well the personal physician model needs to be strengthened.

Finally, the public mental health and private systems need to overlap and work together to establish and monitor quality of care, improve third party coverage, reduce the stigma of mental illness and encourage research. The public mental health sector can continue research into the causes and treatment of mental illness and gather more accurate epidemiological data for analysis and insights.

• EDITOR'S NOTE: Thus it would seem that, among those kind enough to respond to the November question, there are no "turf" issues in the overlap between areas of the public health sector and those of the personal physician. Rather they seem to offer complementary services to our society or similar services to different segments of the society. It was suggested that public mental health care delivery should take more cognizance of the private physician model. Also, it was suggested that perhaps personal physicians should take a larger role in the area of public health, such as learning more about occupational and environmental standards for toxin exposure for the areas in which our patients work. If that's true, should we as health providers also be more concerned about other areas of public safety, e.g., seat belt usage, water and air quality, nuclear war, child or parent abuse? If so, what should we do about it?

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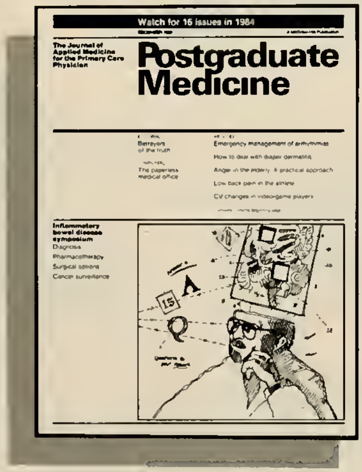
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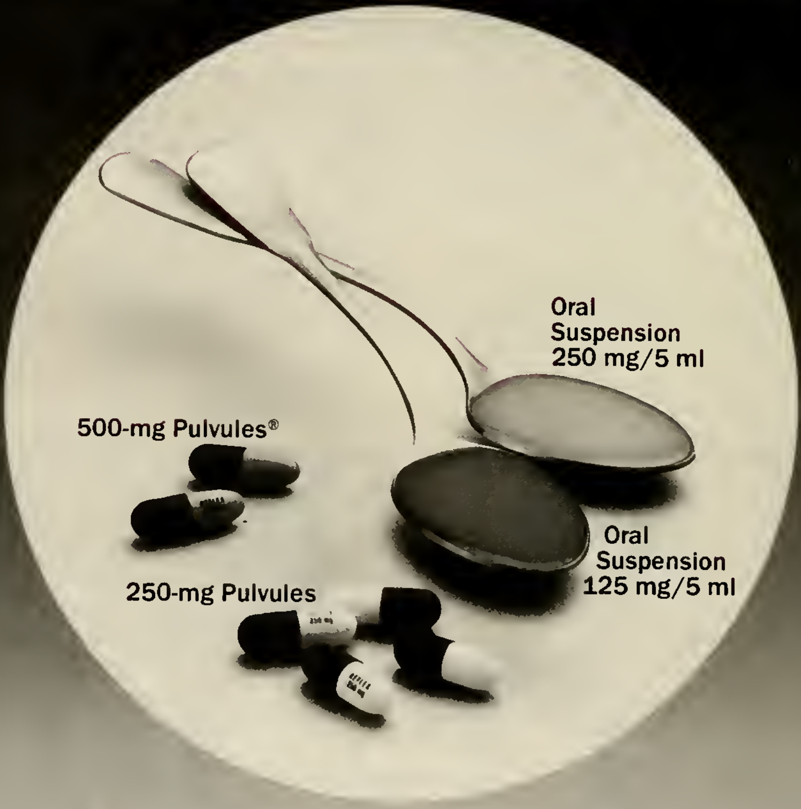

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IN STATE

November 11-14

Advanced Clinical Teaching Skills
Place: Rougemont
Credit: 20 hours Category I AMA and AAFP
Info: Katherine Munning, 407 Crutchfield Street, Durham 27705. 919/471-2571

November 28

Obstetrical Analgesia/Anesthesia
Place: Sanford
Credit: 2 hours Category I AMA and AAFP
Info: R. S. Cline, MD., Central Carolina Hospital, 1135 Carthage Street, Sanford 27330. 919/774-6518

December 4

Duke Tuesday
Place: Durham
Credit: 5 hours Category I
Info: Linda Mace, Box 3707, Duke University Medical Center, Durham 27710. 919/684-2033

December 5

Tourette's Syndrome
Place: Winston-Salem
Info: Child Guidance Clinic, Inc., 1200 Glade Street, Winston-Salem 27101. 919/723-3571

December 6-8

Third Comprehensive Symposium on Breast Disease
Place: Winston-Salem
Credit: 20 hours Catetory I AMA
Fee: $350
Info: Postgraduate Medical Sonics, Bowman Gray, 300 South Hawthorne Road, Winston-Salem 27103. 919/748-4505

January 7-March 1, 1985

Postgraduate Course in Medical Sonics
Place: Winston-Salem
Credit: 35 hours Category I AMA
Info: James F. Martin, M.D., Bowman Gray, 300 South Hawthorne Road, Winston-Salem 27103. 919/748-4505

January 9, 1985

A Model for the Development of Gifted Children
Place: Winston-Salem
Info: Child Guidance Clinic, Inc., 1200 Glade Street, Winston-Salem 27101-2482. 919/723-2482

January 13-16

Beyond Advanced Clinical Teaching Skills
Place: Rougemont
Credit: 20 hours Category I AMA and AAFP
Info: Dr. Katherine Munning, 407 Crutchfield Street, Durham 27705. 919/471-2571

January 26

Sixth Annual Pulmonary Disease Update
Place: Greenville
Credit: 6 hours Category I AMA
Fee: $60.00
Info: Mary Valand, Box 7224, ECU School of Medicine, Greenville 27834. 919/758-5200

OUT OF STATE

November 13

Divorce, Child Custody and the Family
Place: Johnson City, TN
Info: Sue Hutchinson, Quillen-Dishner College of Medicine, Johnson City, TN. 615/928-6426, ext. 204

November 14-17

Williamsburg Symposium on Perinatal Care
Place: Williamsburg
Credit: 12 hours Category I
Fee: $200
Info: Mary Valand, Box 7224, ECU School of Medicine, Greenville 27834. 919/758-5200

November 16

Update: Sudden Infant Death Syndrome
Place: Richmond, VA
Fee: $95
Credit: 7 hours Category I AMA, PREP, ACOG, AAFP
Info: Beth Winn, Box 48 MCV Station, Richmond, VA 23298. 804/786-0494

December 6-15

Review of Clinical Chemistry Seminar
Place: Snowmass, CO
Credit: 40 hours Category I
Fee: $315
Info: Mary Valand, Box 7224, ECU School of Medicine, Greenville 27834. 919/758-5200

January 17-19, 1985

Advanced Ultrasound Seminar
Place: Orlando, FL
Credit: 14 hours Catetory I AMA
Info: James F. Martin, M.D., Bowman Gray, 300 South Hawthorne Road, Winston-Salem 27103. 919/748-4505

January 22, 1985

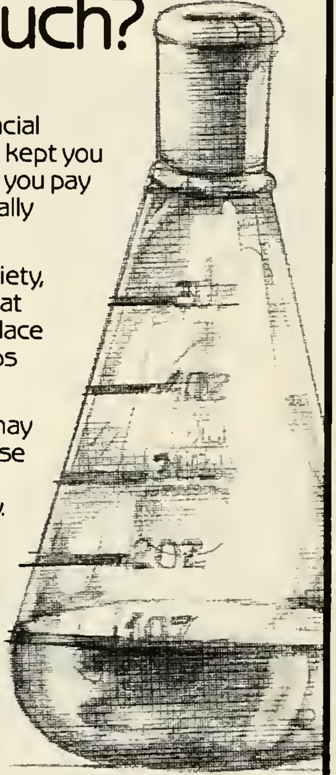
38th Annual Stoneburner Lecture Series: Rehabilitation Medicine
Place: Richmond, VA
Info: Kathy Martin, Box 48, MCV Station, Richmond, VA 23298. 804/786-0494

January 26-31, 1985

Dermatology for Non-Dermatologists
Place: Cancun, Mexico
Info: Division of Dermatology, Box 3135, Duke University Medical Center, Durham 27710. 919/684-2504

January 27-February 2

Surgical Management of Malignant Disease
Place: Vail, CO
Credit: 25 hours Category I AMA
Info: Linda Mace, Box 3707, Duke University Medical Center, Durham 27710. 919/684-2033



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hat Is Medical Auxiliary: Why Belong?

a P. Nance

S a physician, do you understand what being a member
of the North Carolina Medical Society Auxiliary
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ty auxiliaries across the U.S.A.

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ses become a vital part of the health care world. Mem-
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ery through timely and pertinent national publica-
. The national auxiliary provides materials and project
for programs at the state and county levels. State and
ty auxilians take these projects into schools, hospitals,
homes to meet the challenge of filling community
h needs. Promotion of good personal health habits,
y, and fitness form the core of the AMA Auxiliary's
of quality living for all Americans.

e North Carolina Medical Society Auxiliary, in coop-
n with the AMA Auxiliary, has chosen to promote
eness and prevention of child abuse and neglect as its
r focus for 1984-1985. Auxiliaries across North Caro-
re presenting awareness programs to their members,
ators, and community agencies as a result of a child
awareness workshop presented at the annual meeting
ay.

cause child abuse and neglect affects children and
of every socioeconomic level, it is important that
cians and their families make themselves aware and
me involved in positive community involvement
can identify and attack this growing problem.

rth Carolina Auxilians are also being made aware of
er problem. There is now a growing awareness of the
t need for good prenatal and postnatal care if we are to
e a healthy start in life for babies. Increasingly, health
professionals and volunteer health organizations are
oting prenatal and postnatal care through educational
ams and publications. The AMA Auxiliary has de-
ed an informational packet for prenatal and postnatal
and communities are being encouraged to take an
active role in helping to promote personal health habits that will have positive effects on fetal health. Included in the packet is an excellent brochure which is available, free, for distribution in physicians' offices.

As a part of both child neglect and good postnatal care, Auxiliaries are involved in programs to promote the use of child automobile safety restraints. This problem is being addressed in seat loaner programs, school awareness programs, and in promotion of stricter legislation.

In this important election year you can play a part in making sure that medicine's voice is heard. Making your vote count is part of responsible medical citizenship, but you cannot vote if you are not registered! Physicians, physicians' spouses, and eligible family members who are not registered to vote will have no say in electing government officials who will help determine the way medicine is practiced. The American Medical Association Auxiliary is combining efforts with the American Medical Association to conduct a national voter registration drive called PROJECT MEDVOTE to ensure that medicine continues to have a positive effect upon the political process. You can help make PROJECT MEDVOTE a success. If you or your spouse and family are not registered, do it today. Remember that the 350,000 AMA and AMA Auxiliary members plus their spouses, families, and employees equal one million eligible voters.

Child abuse awareness and prevention programs, promotion of good prenatal and postnatal care, and legislation are just a few of the ways in which the Auxiliary can serve as a valuable resource to physicians. Auxilians are involved in promoting a positive image for medicine in your community through many other health education projects.

The PHYSICIAN-SPOUSE TEAM can promote a positive image for physicians in the community, and acts as a strong support system for medical families. Is *your* spouse a member of the Auxiliary Federation: County, State, and National? The North Carolina Medical Society urges every physician to encourage Auxiliary membership for each spouse. Dues can be paid with pre-tax dollars.

For information about membership or for available material, please contact Mona H. Sauls, P.O. Box 27167, Raleigh 27611.

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etters to the Editor

raining/Educating

) the Editor:

Your editorial in the September issue of the *North Caro-*
ia Medical Journal was great. In your sage, erudite
shion, you covered a difficult area very well.

When I served on the Orthopaedic Residency Review
ommittee, we differentiated the two in a much less erudite
shion. We said, "You train bird dogs and you educate
sidents."

I recall your being kidded before about editing "The
uke Medical Journal." I applaud your continuing efforts.
'e are very proud of them. I did wonder if the article in the
me September issue, "Partners in Education in the
cademic Medical Center and the Community Hospital,"
as considered to be "local (North Carolina) advertising."

I echo the sentiments that I hear from my colleagues all
'er the state when I say we do so very much appreciate
hat you are doing for us in editing the *Journal*.

Thomas B. Dameron, Jr., M.D.
P.O. Box 10707
Raleigh 27605

) the Editor:

Your editorial "Training Is No Substitute for Educa-
on" was truly outstanding. I have shared it with several of
y educator friends.

Hervy B. Kornegay, M.D.
238 Smith Chapel Road
Mount Olive 28365

n Omission

) the Editor:

I read with interest the excellent article by Galen S.
agner, M.D. et al. in the September 1984 edition of the
orth Carolina Medical Journal. I practiced neurology in
ıbarrus County for eight years, and can attest to the
cellence of the Duke-Cabarrus affiliation and its unique-
ss in continuing medical education for the physicians in
at part of the state.

I would like to point out an omission. In the early days of
e evolution of the Duke-Cabarrus affiliation, Drs. Ladd
. Hamrick, William Anlyan, and Roscoe (Ike) Robinson
ere most instrumental in the formation of this unique
ogram.

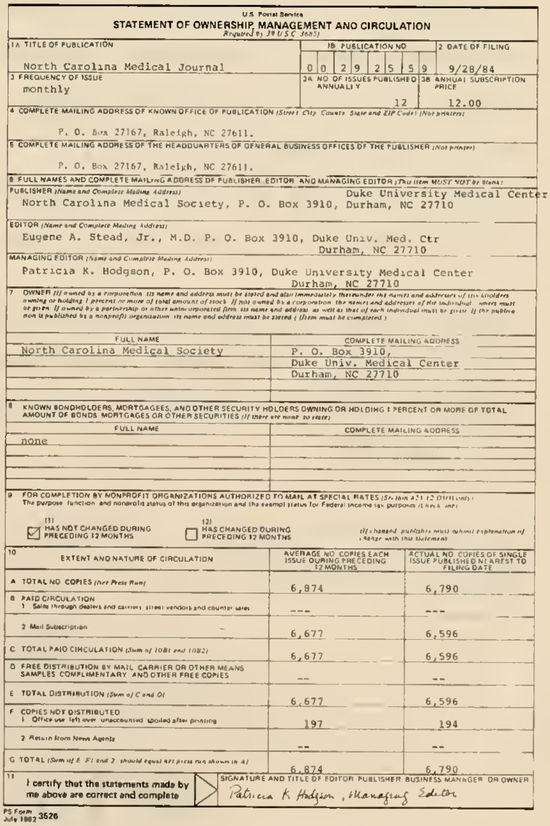
Thanks for an otherwise interesting and informative arti-
.

Marvin P. Rozear, M.D.
Duke University Medical Center
Durham 27710

To the Editor:

I was very pleased to see the letter by Marvin Rozear correcting the oversights in the report of the Duke-Cabarrus Affiliation. Though many were responsible for the inception and the implementation of this program, Ladd Hamrick, Bill Anlyan, and Ike Robinson along with Dr. Stead formed a group which persisted through the years to make certain that this vision became a reality.

Galen S. Wagner, M.D.
Duke University Medical Center
Durham 27710



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1A. TITLE OF PUBLICATION North Carolina Medical Journal	1B. PUBLICATION NO. 0 0 2 9 2 5 5 9	2. DATE OF FILING 9/28/84
3. FREQUENCY OF ISSUE monthly	3A. NO. OF ISSUES PUBLISHED ANNUALLY 12	3B. ANNUAL SUBSCRIPTION PRICE 12.00

4. COMPLETE MAILING ADDRESS OF KNOWN OFFICE OF PUBLICATION (Street, City, County, State and ZIP Code) (Not printers)
P. O. Box 27167, Raleigh, NC 27611.

5. COMPLETE MAILING ADDRESS OF THE HEADQUARTERS OF GENERAL BUSINESS OFFICES OF THE PUBLISHER (Not printer)
P. O. Box 27167, Raleigh, NC 27611.

6. FULL NAMES AND COMPLETE MAILING ADDRESS OF PUBLISHER, EDITOR, AND MANAGING EDITOR (This item MUST NOT be blank)

PUBLISHER (Name and Complete Mailing Address)
North Carolina Medical Society, P. O. Box 3910, Duke University Medical Center
Durham, NC 27710

EDITOR (Name and Complete Mailing Address)
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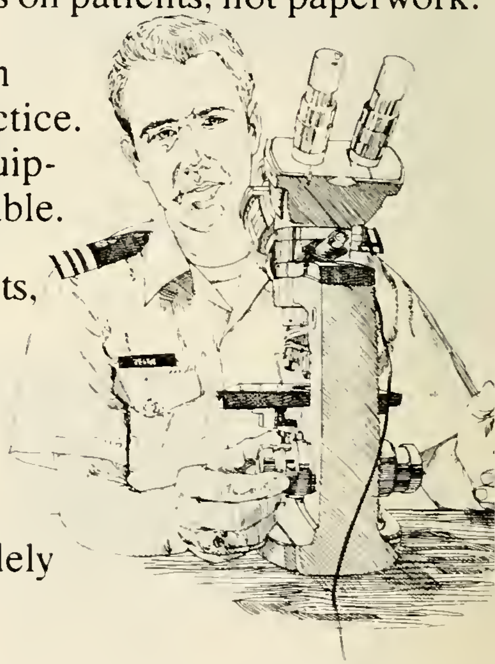

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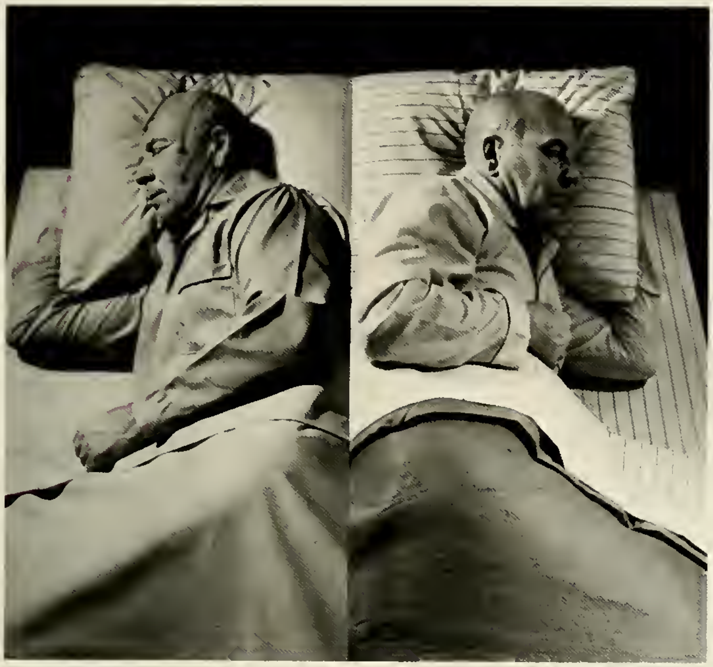

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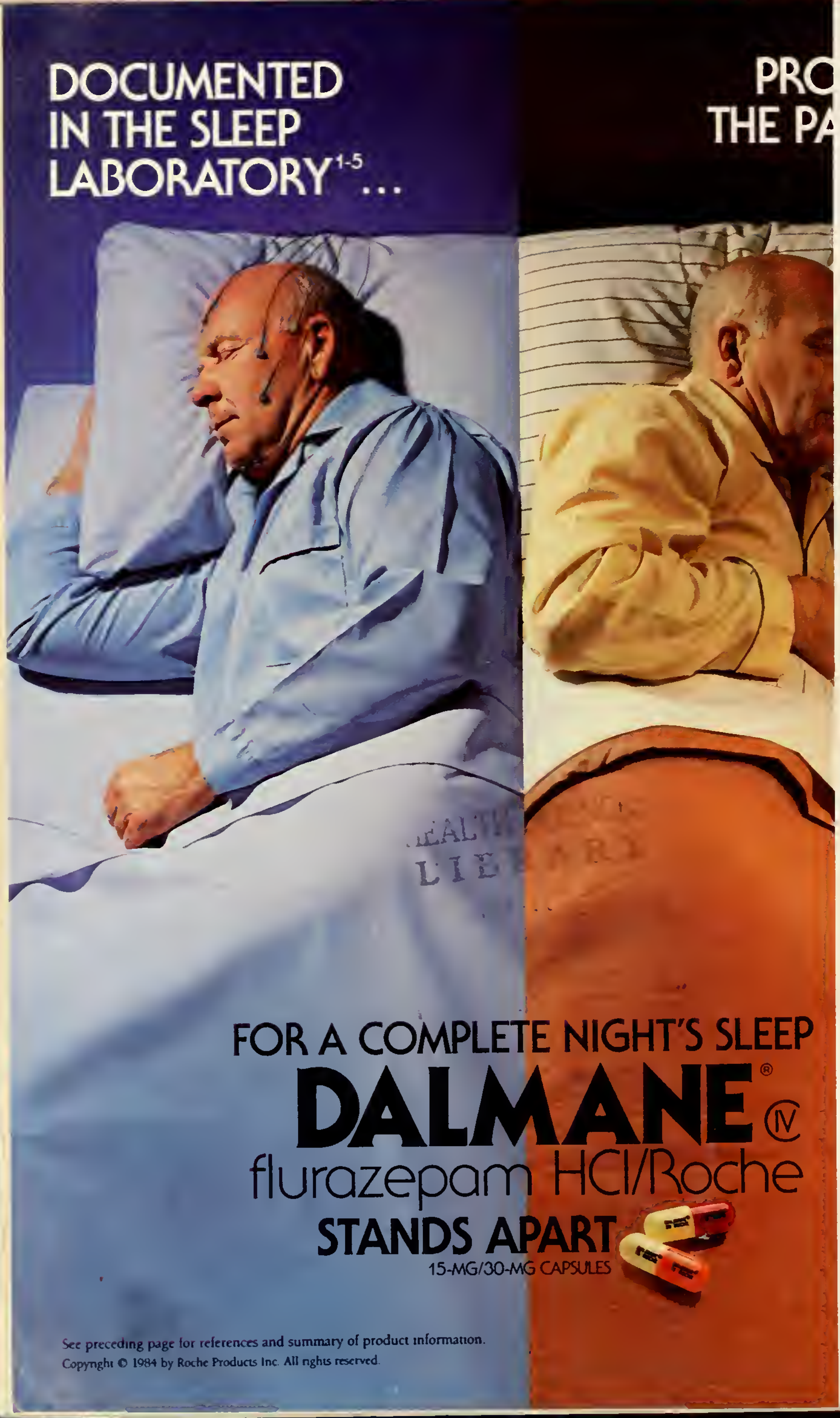

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SCIENTIFIC ARTICLE

Treatment of Metrizamide-Induced Mania

J. Ray Israel, M.D. and John Prather, M.D.

• *A patient with chronic arachnitis underwent a cervical CT with metrizamide infusion. This article tells the story of the next eight weeks of treating her side effects.*

MANIA has been reported to be secondary to a number of organic illnesses as well as precipitated by several drugs. Stimulants, including cocaine and amphetamines, phencyclidine, L-dopa, steroids and bromocriptine have been associated with producing mania. Various physical illnesses are also associated with producing mania: toxic confusional states, multiple sclerosis, tumors, particularly in the diencephalon and parasaggital areas, viral encephalitis, hemodialysis, syphilis and epilepsy. The alert clinician must take all of these possibile etiologies into consideration before diagnosing bipolar illness even with a history of depression.

The following case report illustrates the treatment of an organic affective disorder, mania induced by metrizamide. Although there is one other recent report of mania induced by this substance, to our knowledge this is the first reported case that did not resolve with supportive therapy and required extensive treatment. This patient responded to treatment with Lithium Carbonate.

Ms. W, a 38-year-old woman, was admitted to the neurosurgery service with acute complaints of shortness of breath, weakness and trouble standing. Ms. W had a past history of multiple neurosurgical admissions for syringomyelia with repeated cervical, thoracic and lumbar laminectomies and shunting procedures for decompression of her syrinx. A cervical CT with metrizamide infusion was obtained. Findings were consistent with chronic arachnitis with decompression of her syrinx. Within 48 hours of this procedure, Ms. W was confused, disoriented with a euphoric mood. She indicated that she was "jogging and dancing" despite an inability to ambulate without support. A psychiatric consult was obtained and reported the patient seemingly aware with elective mutism and observed smiling and laughing inappropriately. There was no past history nor family history of affective disorder. The differential diagnosis included organic brain syndrome, delirium, atypical dissociative disorder and hypomania. Haldol 2 mg p.o. t.i.d. was initiated as was an organic workup to rule out etiologies of delirium. Her workup (CT scan, EEG, LP, CBC, electrolytes, urine and blood cultures) was essentially normal. Lumbar puncture results — protein 600 mg/dl, glucose 63 mg/dl, cell count WBC 355 with 75% monocytes — were felt consistent with chronic arachnitis. Fungal and bacterial cultures were negative. On follow-up over the next two weeks, Ms. W continued her elated mood with pressured speech and hyperactivity. She was fully oriented and alert. She maintained the delusional percept that she was able to jog and dance. It was decided that her psychiatric symptoms were not secondary to delirium and she was transferred to the psychiatry unit and started on oral fluphenazine hydrochloride 2 mg q.i.d. On the psychiatry unit, her manic symptoms persisted and Lithium Carbonate 300 mg q.i.d. was initiated, maintaining a Lithium level of 0.7 mEq/l. Gradually her manic symptoms dissipated and fluphenazine hydrochloride was discontinued. As her mood became less elevated, Ms. W spoke of depressive themes and her mood became depressed. She was stabilized on trimipramine 150 mg daily with continuation of Lithium Carbonate. Her mental status normalized and she was discharged eight weeks after her cervical CT with metrizamide infusion.

Metrizamide has been associated with several neuropsychiatric side effects including anxiety, depression, drowsiness, confusion and perceptual changes. A higher frequency of these side effects has been found with cervical and thoracic myelography rather than lumbar myelography. With the common usage of metrizamide in radiographic procedures, knowledge of its neuropsychiatric side effects may be increasingly important.

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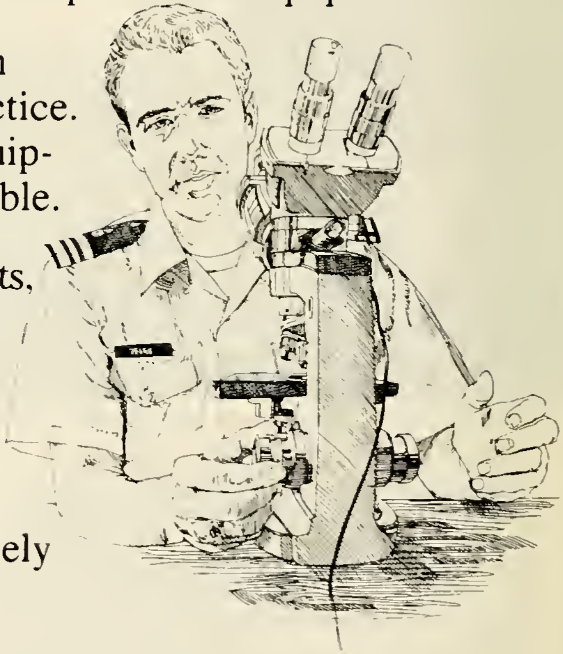

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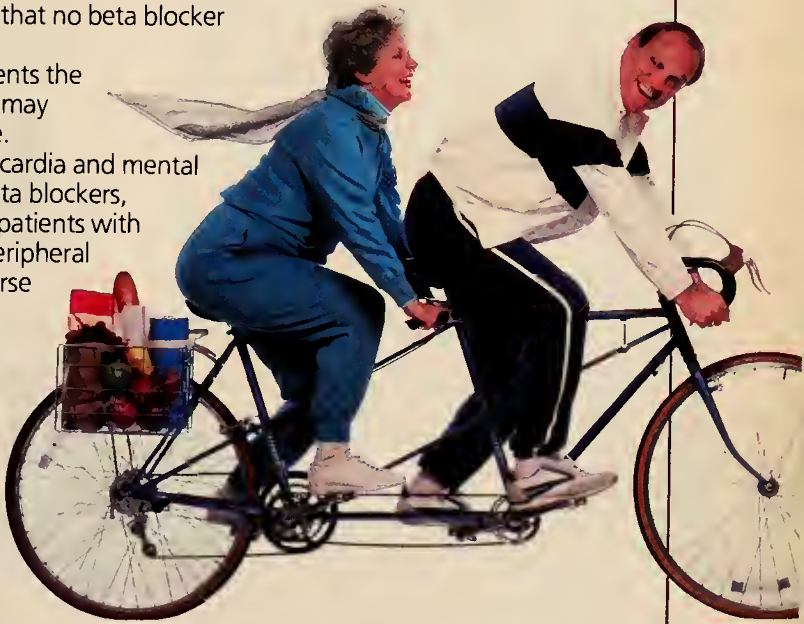

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EDITORIAL

Angioaccess Systems for Prolonged Systemic Therapy of Cancer Patients

William W. Shingleton, M.D.

THE need for easy access to the systemic circulation of patients with malignant disease has increased in importance as a result of the increased use of palliative and curative chemotherapy, the administration of antibiotics, blood and blood products, and intravenous alimentation in these patients. Intermittent venipuncture for these purposes can require considerable effort by the treatment team and discomfort to the patient. Many patients require these forms of therapy over a period of months, or a year or more. The development of new procedures and equipment to address this problem represents a significant advance in the area of cancer patient management. More efficient management of certain other chronic diseases requiring frequent vascular access has also resulted from these technological advances.

Efforts to solve the problem of vascular access were made in the early 1970s by creating an arteriovenous fistula in patients using autologous vein or synthetic material. This approach, although helpful, was found to be limited in its usefulness due to a high incidence of occlusion (30% to 60%). In 1973 Broviac developed a silicone rubber catheter for prolonged venous cannulation and this catheter was modified by Hickman in 1975 by increasing the internal diameter. These silastic catheters were tunneled under the skin distal to the point of entry into a vein (external jugular, axillary, subclavian), with the tip of the catheter located in the superior vena cava. Subsequently, double lumen catheters were introduced which permitted greater flexibility in administering different drugs or other intravenous products simultaneously.

Studies indicate that Hickman-Broviac catheters remain patent for long periods (12-18 months) without occlusion. However, because the catheters require an exit point in the skin, infection has been reported to occur in a range of 10-25 per cent in various patient groups. This problem has led to the development of a totally implanted injection port system that allows for both blood sampling and chemotherapy administration. The system consists of an injection reservoir with a silicone rubber septum connected to a silastic catheter which is positioned into the superior vena cava via the axillary, subclavian, or external jugular vein. A special needle (Huber) is used for insertion into the reservoir located in the subcutaneous tissue of the chest wall, and through this needle blood can be withdrawn, or drugs or other products can be given as indicated. The system is filled with heparinized saline to sustain patency between episodes of active use.

To date, several studies on the use of totally implanted venous access systems for use in cancer patients have been carried out. The largest study involving the evaluation of the device has been performed by investigators at the University of Michigan in Ann Arbor.[1] They indicate that over 100 such devices have now been implanted with more than 29,000 days of access, and with a complication incidence of approximately .6 per 1,000 days of access. Another study reported by Bothe et al,[2] involving 74 patients utilizing a similar implanted venous access system, indicates a somewhat higher incidence of complications. One of the most promising features of these devices is the finding that they can be utilized with a very low infection rate in chronically ill patients who have a depressed immune system. In addition, the device allows successful blood sampling when needed and, at the same time, provides the patient freedom of activity between periods of drug administration. This system, therefore, appears to be a highly reliable, effective, and convenient system with an acceptable complication rate in compromised chronically ill patients. The cost of the system, including installation, is estimated in the range of $500 to $600. Due to cost and other considerations, the system should obviously be used in carefully selected patients whose need for long term angioaccess justifies the cost involved.

A related system has been developed and evaluated for intra-arterial chemotherapy. This system, consisting of a catheter connected to an implantable infusion chamber, is powered by charged freon, has a chamber capacity of 50 milliliters, and a fixed rate of delivery of 3 milliliters a day. The pump is silent, small (10 x 3 cm), and lightweight (180 g). It is refilled and automatically recharged by simple percutaneous injection through the skin every two weeks. The system has been primarily used for perfusion of the liver via the hepatic artery for metastatic liver carcinoma. Balch,[3] who has had a large experience with the device in over 200 patients, has found the system to be highly reliable and largely devoid of the complications associated with conventional intra-arterial therapy, such as sepsis, thrombosis, and misplacement of the catheter. This device is expensive (estimated $10,000-12,000) however, and its value, due to the limited effectiveness of chemotherapy drugs available for use in the system, has yet to be determined.

The angioaccess systems described above for long term intravenous and intra-arterial chemotherapy represent a

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significant advance in the therapeutic management of cancer patients. In the past, one of the major problems associated with long term access systems has been the problem of infection. Evidence now suggests that the newer implantable systems have markedly reduced the incidence of this complication. The additional advantage of these implantable systems is the provision of a portal for long term administration of antibiotics, blood and blood products, and intravenous nutritional products when these are needed.

The use of the presently available implantable device for intra-arterial chemotherapy at this time remains experimental, since the value of this approach for therapy of either primary or metastatic tumor remains questionable.

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EDITORIAL

Should We Change Our Admission Policies?

John B. Graham, M.D.

IT is easy to despair about our future. Nuclear bombs, exploding populations in the Third World, "acid rain," deforestation, hazardous chemicals, unemployment, crime in the streets and by computer, "greenhouse effect," crooked politicians, drug dealing, rapacious property developers, strikes, famines, floods, etc., etc., etc. How can we cope? For one thing, we might try using our intellectual resources more sensibly. These resources consist of the collective minds of our citizens. Two things could be done to utilize them more effectively. We could try to assure that all of the more able minds are trained, and also try to be certain that these trained minds are distributed more effectively for the benefit of our society.

Making certain that the more able are not overlooked early in life is the responsibility of the family and the schools. It is of course important to train the less able, but we are culpable if we fail to train all the more able, those on whom the success of our society depends. It is my impression that we tend to leave the training of our best young people to chance on the theory that they will probably turn out all right. This is very short-sighted.

Let us consider the human trait which we call "IQ." We don't know exactly what it represents, but it is easy to measure and study. We know that high values of IQ tend to be heavily concentrated in a section of the population which everyone agrees also contains our most intelligent citizens. Values of IQ are distributed in what is called a Gaussian (or "normal") fashion. The "mean," or average, value of IQ is given the number 100, and the standard deviation of IQ is 15. This means that 66% of all people have IQs between 85-115. Only 17% have values above 115, and only 5% have values above 125. Our rare geniuses have values above 140.

Most of the leaders in any field are drawn largely from those on the upper side of IQ 115. This means that the success of our democratic society depends heavily upon the adequate functioning of less than 17% of our citizens. A society which does not attempt to find and train all of these persons is very foolish indeed.

The evidence is clear that intelligence is unrelated to sex. Whether there is an effect of race on intelligence has been hotly debated for two generations, but I think the question is unimportant. What really matters is that all persons of both sexes and all races have access to adequate training and be encouraged to obtain it.

There is not a surplus of highly able people, and the deficit will become larger as our society becomes more involved with technology.[1] Able women and minority citizens have not always been treated fairly by the schools and employers of our country, and the time is long past when we can afford a loss of talent for reasons of prejudice. I am pleased that in my lifetime we have been moving in the direction of equality, but we have a long way to go.

What is less apparent and, therefore, more troublesome is our failure to perceive the *maldistribution* of our most talented people. Since only 17% have IQs greater than 115, and 5% have values greater than 125, we should be very careful to see that these talents are not overlooked or underutilized. Ignoring short term fluctuations, our country of 250 million people will produce (at our present birth rates) about 3,600,000 babies a year, the yearly output being referred to as a "cohort." Not all members of a cohort who are capable of doing so will finish high school or attend college. But it seems reasonable to estimate that of the 612,000 in each cohort with IQs greater than 115, 500,000

From the Department of Pathology, UNC School of Medicine, Chapel Hill 27514.

[1] A colleague who has retired has opined that it now requires an IQ of at least 120 to deal adequately with the complexities of medical care, housing, stocks and bonds, income tax, etc.

might complete advanced training. And perhaps 130,000 of the 180,000 with values above 125 will do so. It is these persons on whom we must depend for solutions to the problems which I listed in the beginning.

What are the most important areas of society into which our most talented people should move? Certainly politics, the civil service, the military, and industry are vital areas demanding talent of the highest order. The recent history of our country suggests that these fields have not been receiving the talent that they need. But what about law and medicine, the ancient professions?[2] I believe that law and medicine are much less important than many of my contemporaries, and are not professions which should draw off large numbers of our ablest citizens. But what is actually happening?

Each year the law and medical schools of our country admit more than 40,000 of our ablest graduates. Most of the matriculants come from the upper 5% of the IQ range, a pool of only 130-180,000 in current cohorts (the 1960-62 babies). Thus, it appears that more than one quarter of the best talent becoming available is going into law and medicine. Why? Because we allow the invisible hand of the market place to work its will!

The ancient professions have always been stepping stones socially — acceptable, stable and safe. Now they are also lucrative! It is bad enough to have so many bright doctors on hand that more procedures are done than are necessary in order to protect against malpractice and to maintain incomes. And that there are so many bright and underemployed lawyers that they are causing grid-lock in our courts with unnecessary litigation. But the real danger to our society is not from these actions. It is that these talented people have been removed from general circulation and are not available to tackle more important tasks.

The market mechanism, which became sacrosanct in our country after World War II under the rubric of "free enterprise," is efficient in making short term corrections in our economy. But "bottom line" thinking does not lead to good planning for the long haul. Such thinking has in fact been the cause of many of the problems I mentioned in the first paragraph. In a few years we may find ourselves desperate for talent, because we have allowed too much of it to become sequestered in less essential occupations.

The Dutch are both wiser and more decisive than we. I don't know how they handle admission to law school, but Professor Veltkamp of Leiden tells me that they do not allow medical schools to siphon off too much top talent. Students in the Netherlands are admitted to medical school by lottery.

All students graduating from high school (at least equivalent to our junior college) are eligible for admission to medical school, a six year program. This year about 4000 have applied for 1500 slots. The evaluation process is complex and not entirely random but every applicant stands a chance of admission, including those who have never had a course in science. When such persons are selected, slots are held until deficiencies in science have been remedied.

The Dutch scheme has several consequences. It produces a much wider range of abilities in the medical profession than we have in the USA. This means, among other things, that the profession will contain many more members who are as interested in the personal problems of their patients as in the intellectual problems of their patients' illnesses. The most important effect, however, is that it forces many very able Dutch men and women to move into other sectors of society. This means that the Dutch have a better chance than we to expect future legislatures, military high commands, cabinets, and industries to contain more nearly adequate numbers of the most talented citizens.

Is it any wonder that the Dutch have managed to survive in a hostile environment and to prosper for 600 years? I wish that I felt as hopeful about our own country.

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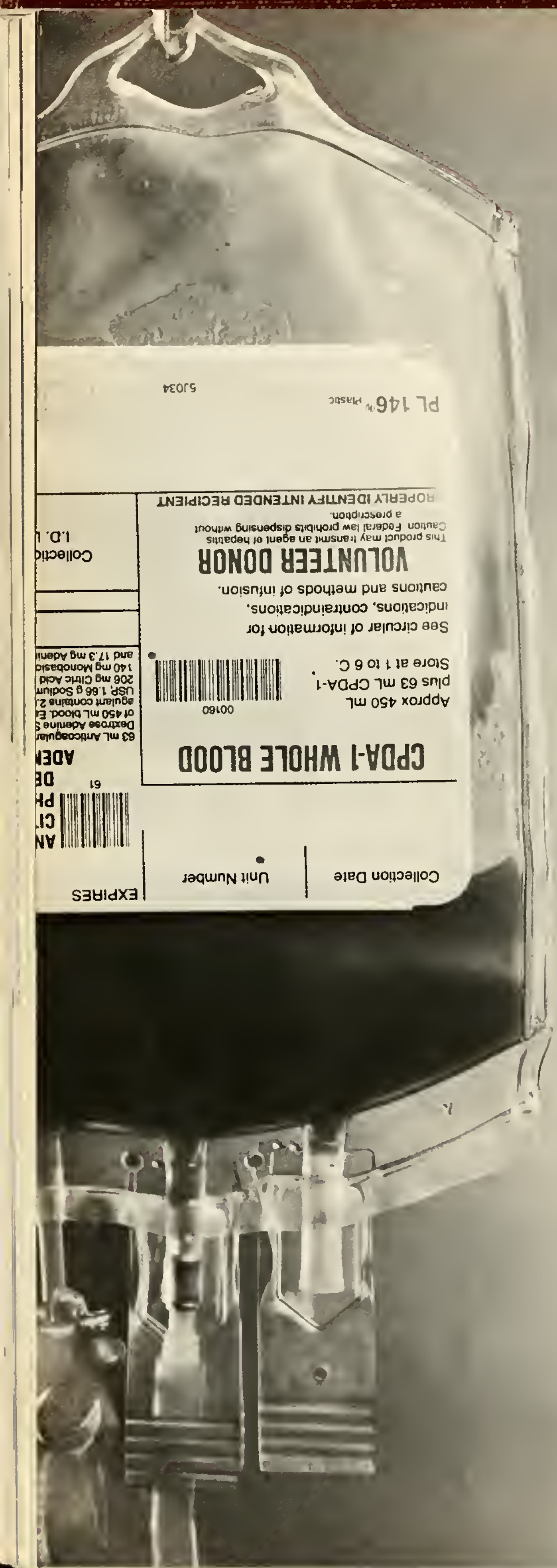
[2] These are referred to as the "ancient professions" because it was the joining together of the faculties of law, medicine, and theology which led to the establishment of the universities in Europe at the end of the Middle Ages.



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EDITORIAL

Hypoglycemia: A Handle That Rarely Fits

Warner M. Burch, M.D.

WHAT is hypoglycemia? I find myself addressing that question frequently. Hypoglycemia must be defined operationally as a blood glucose low enough to produce neuroglycopenic and/or adrenergic symptoms. Patients having brain cell failure from hypoglycemia present with an inability to concentrate, confusion, incoherent speech, headache, blurred vision, bizarre behavior, focal or generalized seizures, stupor, coma, and finally death. Adrenergic symptoms relate to homeostatic mechanisms that stimulate release of epinephrine, norepinephrine, cortisol, glucagon, and growth hormone which raise blood glucose in response to hypoglycemia. These homeostatic responses produce the most striking symptoms and include sweating, palpitations, hunger, tremor, tachycardia, and anxiety. These are the early warning signs of hypoglycemia whereas most of the neuroglycopenic symptoms occur when the hypoglycemia is more profound. Two other characteristics of hypoglycemic symptoms are their episodic nature and relief of symptoms with glucose ingestion. Each episode of hypoglycemic symptoms lasts for minutes to hours because either counter-regulatory responses spontaneously raise plasma glucose or the patient eats food to raise the plasma glucose. However, relief of symptoms with food or beverage does not make a diagnosis of hypoglycemia since this is not specific for hypoglycemia.

A diagnosis of hypoglycemia is made when the patient has the symptoms listed above *and* plasma glucose levels are <60 mg/dl after overnight fast (fasting hypoglycemia) or <50 mg/dl on an oral glucose tolerance test (reactive hypoglycemia).[1] Symptoms alone do not make a diagnosis of hypoglycemia. Most symptoms reflect a nonspecific increase in adrenergic discharge. Neither do low plasma glucoses alone establish the diagnosis of hypoglycemia *unless there are accompanying neuroglycopenic or homeostatic symptoms*. Much confusion regarding hypoglycemia can be avoided if these criteria for the diagnosis are met. Fasting hypoglycemia requires full evaluation as to organic causes (e.g., insulinoma).

Many patients make their own diagnosis of hypoglycemia, attributing the symptoms of adrenergic discharge, mental and physical fatigue, and weakness that may or may not be relieved by glucose-laden food to "hypoglycemia." The lay press and media have fanned the fires by popularizing this "entity." Physicians have confused the issue themselves by not having a study that can mimic the conditions under which these patients have symptoms.

The time-honored oral glucose tolerance test (GTT) has many problems.[2] At least 24% of healthy inductees into the armed forces have 2 hr plasma glucose <60 mg/dl, and 5% have plasma glucose <50 mg/dl without any symptoms. In another study of 650 patients who had no symptoms before or during GTT, 10% had plasma glucose values <47 mg/dl.[3] The frequency of biochemical hypoglycemia is the same for patients who present for evaluation of reactive hypoglycemia as it is for the normal population. Furthermore, most of the patients being evaluated for hypoglycemia with the GTT have symptoms when their corresponding plasma glucoses are in the normal range.[4] The 75-100 g load of glucose is not a physiological challenge since this is not what subjects eat at meals. These factors make interpreting the GTT results difficult. The GTT has a place in making a diagnosis of diabetes mellitus but its use in evaluating hypoglycemia is very questionable. An attempt to use mixed meals (¼-⅓ total daily calories distributed as 50% CHO::20% protein::30% fat) as a challenge that might precipitate symptoms has shown that those patients who have biochemical hypoglycemia on a GTT do not have low plasma glucose after a mixed meal yet have the same adrenergic symptoms.[5] Thus, low plasma glucoses can not be confirmed to be related to symptoms in over 95% of patients in whom the diagnosis of reactive hypoglycemia is tentatively made.

The hordes of patients with "non-hypoglycemic hypoglycemia" or "pseudohypoglycemia" who present to the endocrinologist's practice with the diagnosis of reactive hypoglycemia is astounding. What to say and what to recommend to these people who are looking for a handle to label their symptoms and a means of controlling these symptoms requires clinical discernment. These patients (most often females ages 20-45) have stresses either recognized or not acknowledged. Many have chronic fatigue and somatic complaints lasting days and weeks that do not conform to typical episodic spells of true hypoglycemia. How well these patients are handling stress is reflected in the "hypoglycemic" symptoms. Labeling these patients as having reactive or functional hypoglycemia may be an expedient handle to pacify the patient (and the physician) as to the "physical" cause of the symptoms. However, several weeks or months later, that handle loses its usefulness since the symptoms usually persist or recur. A tender ear and a soft tongue giving an honest assessment of the particular situation is a beginning step in managing these patients. A 120 gm carbohydrate diet low in simple sugars and instructions from an innovative dietician are helpful and should be prescribed. For the recalcitrant patient who has failed to improve despite discussion and diet, psychiatric referral may be helpful.

From the Departments of Medicine and Pharmacology, Duke University Medical Center, Durham 27710.

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EDITORIAL

How the Handle Fit in 1960

Eugene A. Stead, Jr., M.D.

IT has long been recognized that patients with spontaneous or exercise-produced hyperventilation have irritable nervous systems. The fact that the respiratory center does not slow down respiration when enough CO_2 has been lost to produce alkalosis is a sign of incoordination in the regulation of respiration. The patient may be taught to recognize the symptoms of hyperventilation and he may prevent them by breathing into a closed container, as a paper bag, but he will not recover normal smooth control of respiration unless the nervous system functions more normally. He can learn to understand his symptoms and tolerate them and be interested in the situations producing them, but this will not prevent uneven respiratory regulation in times of stress.

The patient with this kind of symptomatology is usually telling the physician two things: (1) his sensory nervous system is unusually sensitive to changes in environment so that changes commonly ignored are now noticed and (2) homeostatic regulation is poor so that swings in the internal environment are greater than normal. Both are responsible for a rather diffuse symptomatology. Examination of the patient shows that he has many evidences of poor homeostatic control. He has cold hands and feet, he sweats profusely in certain areas, goose flesh appears and disappears, and the blood pressure rises too high at times and frequently falls more than expected under the stress of standing. History confirms irregular function of the gastrointestinal tract and the bladder, and difficulty in sexual activities. The laboratory shows both high and low concentrations of blood sugar, the cholesterol varies and the electrocardiogram is unstable.

The physician is likely to attribute the symptoms to the area of his own greatest interest. If he is studying the phenomenon of hyperventilation, this will be the diagnosis. If he is interested in blood sugar regulation, he will believe that he has an instance of functional hypoglycemia. If he is interested in postural reactions, he will attribute considerable importance to the fall in pressure on standing. If he is a gastroenterologist, he will be struck by many similarities between his patient and the "dumping syndrome." If he is a cardiologist, he will be intrigued by the changing electrocardiographic pattern. Because of the dyspnea, and the marked changes in pulse rate, he will summarize his impressions by the diagnosis of "effort syndrome."

In time, the physician is impressed with how little the basic complaint is helped by attention to one aspect of this diffuse disturbance, and he realizes that the patient is describing his overall problem in sensory pickup and regulation of body function, and not a specific disturbance in a single function. He then needs to know what do doctors know about this type of illness and what is its course.

Some persons are born with a sensitive nervous system in which impulses "sprangle" (a fine Carolina term), and in which most sensory impulses cause widespread motor discharges. These patients may always be conscious of their body and the changes in their internal environment. Once they learn about their makeup, they should approach the doctor with the question: "Are these sensations disease or is this I?" Both patient and doctor have to recognize the biologic organization of these particular patients and not be irritated because it differs from others.

The organization of the nervous system and its ability to regulate the internal environment varies greatly in a given person (and, remember, he is different from all other persons) from time to time. The degree to which the system is capable of standing stress without breaking down is a measure of the stability of the system. The system may break down because (1) the stress has become too great or (2) the system is less capable of standing the same stress. By stress, we mean any load, physical, emotional, mental or social which requires additional activity in the mechanisms stabilizing nervous activity and the internal environment of the body. By changes in the system, we mean any disturbance in cell function — be its etiology viral, bacterial, toxic, physical trauma, heat, cold or other physical agents; or caused by alteration in function of the nervous system from emotional or psychic reactions to the environment.

Reprinted from Disease-A-Month 1960;101:25-29.

Many changes in the biology of the patient may occur which are not obvious when the organism is under minimal stress. If we wish to determine the presence of change we must find out if the ability of the organism to stand stress has changed. The stress does not in itself produce the disease, but it does make its presence obvious. A man with moderate coronary disease may have no angina during a relatively sedentary existence. Sudden heavy exertion may produce angina. The exercise has not produced coronary disease. It has merely demonstrated its presence. A patient in his forties may develop urticaria in certain situations in which he never before had difficulty. These situations, which formerly did not end in urticaria, do not produce the biologic changes responsible for the appearance of urticaria, but they do demonstrate that these biologic changes have occurred in the organism. From a practical point of view, the patient needs to know what situations he must avoid in view of the changes in his body.

The fact that patients are able, by their wide testing of themselves in the stresses of living, to find out that their bodies have changed when all of the physician's laboratory findings show no change is not surprising. The patient is reporting the results of a series of biologic assays, and we know from experience that many biologic assays have a sensitivity far beyond that of our present chemical methods. In addition to this difficulty, we do not know all of the active ingredients of any biologic system. Therefore, it is not surprising that the patient describes to us symptoms that we do not understand.

Our knowledge of the symptomatology produced by discrete lesions in the nervous system is still in its infancy. As one watches the changes which occur in an aging population, it is clear that many of their reactions are determined by central nervous system disease. Many of the mechanisms of homeostasis which are reversibly disturbed in the person without destructive disease in the nervous system are permanently crippled in patients with destructive changes in the nervous system. In the early stages of destructive illness, symptomatology may be diffuse and hyperventilation may be present. Only a long followup will determine the kind of illness we are dealing with.

Patients with problems in homeostasis who have symptoms in part from hyperventilation may be grouped as follows:

1. Persons born with sensitive sensory systems and more widespread motor discharges than occur in the average person. These people will always have wide swings in internal environment and in symptomatology. The degree of symptomatology will parallel the physical, emotional, social and economic forces to which they are submitted. The doctor recognizes that these patients are different from the norm, and he teaches them to be tolerant of their bodies. The patient learns what situations provoke undue symptomatology and avoids them.

2. Persons with good homeostatic mechanisms in whom the load becomes too great for the homeostatic mechanisms functioning at a level commonly found in the population. In some way, the load must be lightened.

3. Persons who normally have carried the stress of living without difficulty but who, because of a well-defined illness, can no longer manage the situation. We see this in infections, hepatitis, thyrotoxicosis, pernicious anemia and all other illnesses. Given time, these patients return to their former baseline, provided the precipitating disease can be controlled. Until the usual resiliency returns to the body, additional protection is needed.

4. Persons who can date the time when the body changed to a state of increased sensitivity in the sensory and motor systems. A history of previous episodes in the patient or family is common. At some unpredictable time the patient reverts back to his more normal state. We usually describe these as episodes of self-circumscribed illness characterized by fatigue, depression, loss of sexual drive, unusual sensitivity of the nervous system and poor regulation of the internal environments. Because they feel so bad, many of these patients say that they are carrying heavy loads. The loads certainly seem heavy to the patient, but objective evidence to this effect may not be found. Many of these patients feel quite desperate. They project the future in terms of the present and feel that some organic treatable disease must be found or they will not be able to continue living. The doctor has the great advantage of knowing that the patient will improve in time even if nothing is done. He can help the patient live through the present without anxiety because he knows that the future is not a projection of the present. The doctor uses whatever symptomatic therapy is needed until recovery occurs. He advises the patient against making decisions which will cause large changes in his pattern of living until he feels well again. He uses whatever symptomatic therapy is needed for the patient and himself to live until recovery occurs.

5. Patients with destructive organic disease without localizing signs. This can range from cerebrovascular disease to diffuse carcinomatosis.

6. Patients with a major psychosis may pass through this stage of diffuse irritability of the nervous system.

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Reduces angina attack frequency*
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Increases exercise tolerance*
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CARDIZEM®
(diltiazem HCl)

THE BALANCED CALCIUM CHANNEL BLOCKER

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2/84

*Cardizem is indicated in the treatment of angina pectoris due to coronary artery spasm and in the management of chronic stable angina (classic effort-associated angina) in patients who cannot tolerate therapy with beta-blockers and/or nitrates or who remain symptomatic despite adequate doses of these agents.

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PROFESSIONAL USE INFORMATION

cardizem®
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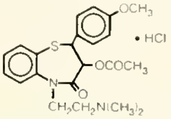
30 mg and 60 mg tablets

DESCRIPTION

CARDIZEM® (diltiazem hydrochloride) is a calcium ion influx inhibitor (slow channel blocker or calcium antagonist). Chemically, diltiazem hydrochloride is 1,5-Benzothiazepin-4(5H)one,3-(acetyloxy)-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-, monohydrochloride,(+)-cis- The chemical structure is



Diltiazem hydrochloride is a white to off-white crystalline powder with a bitter taste It is soluble in water, methanol, and chloroform It has a molecular weight of 450 98 Each tablet of CARDIZEM contains either 30 mg or 60 mg diltiazem hydrochloride for oral administration.

CLINICAL PHARMACOLOGY

The therapeutic benefits achieved with CARDIZEM are believed to be related to its ability to inhibit the influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle

Mechanisms of Action. Although precise mechanisms of its antianginal actions are still being delineated, CARDIZEM is believed to act in the following ways

1 Angina Due to Coronary Artery Spasm CARDIZEM has been shown to be a potent dilator of coronary arteries both epicardial and subendocardial. Spontaneous and ergonovine-induced coronary artery spasm are inhibited by CARDIZEM
2 Exertional Angina CARDIZEM has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal exercise work loads

In animal models, diltiazem interferes with the slow inward (depolarizing) current in excitable tissue. It causes excitation-contraction uncoupling in various myocardial tissues without changes in the configuration of the action potential Diltiazem produces relaxation of coronary vascular smooth muscle and dilation of both large and small coronary arteries at drug levels which cause little or no negative inotropic effect. The resultant increases in coronary blood flow (epicardial and subendocardial) occur in ischemic and nonischemic models and are accompanied by dose-dependent decreases in systemic blood pressure and decreases in peripheral resistance

Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, diltiazem decreases sinoatrial and atrioventricular conduction in isolated tissues and has a negative inotropic effect in isolated preparations In the intact animal, prolongation of the AH interval can be seen at higher doses

In man, diltiazem prevents spontaneous and ergonovine-provoked coronary artery spasm It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative inotropic effect; cardiac output, ejection fraction, and left ventricular end diastolic pressure have not been affected There are as yet few data on the interaction of diltiazem and beta-blockers Resting heart rate is usually unchanged or slightly reduced by diltiazem.

Intravenous diltiazem in doses of 20 mg prolongs AH conduction time and AV node functional and effective refractory periods approximately 20% In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block Diltiazem-associated prolongation of the AH interval is not more pronounced in patients with first-degree heart block In patients with sick sinus syndrome, diltiazem significantly prolongs sinus cycle length (up to 50% in some cases)

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PR interval, but has not usually produced abnormal prolongation There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients.

Pharmacokinetics and Metabolism. Diltiazem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive first-pass effect, giving an absolute bioavailability (compared to intravenous dosing) of about 40% CARDIZEM undergoes extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the urine In vitro binding studies show CARDIZEM is 70% to 80% bound to plasma proteins Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, hydrochlorothiazide, phenylbutazone, propranolol, salicylic acid, or warfarin Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3 5 hours Desacetyl diltiazem is also present in the plasma at levels of 10% to 20% of the parent drug and is 25% to 50% as potent a coronary vasodilator as diltiazem Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 ng/ml. There is a departure from dose-linearity when single doses above 60 mg are given, a 120-mg dose gave blood levels three times that of the 60-mg dose. There is no information about the effect of renal or hepatic impairment on excretion or metabolism of diltiazem.

INDICATIONS AND USAGE

1 **Angina Pectoris Due to Coronary Artery Spasm.** CARDIZEM is indicated in the treatment of angina pectoris due to coronary artery spasm CARDIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occurring during attacks).
2 **Chronic Stable Angina (Classic Effort-Associated Angina).** CARDIZEM is indicated in the management of chronic stable angina CARDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise tolerance

There are no controlled studies of the effectiveness of the concomitant use of diltiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

1 **Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0 48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
2. **Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
3. **Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension
4 **Acute Hepatic Injury.** In rare instances, patients receiving CARDIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes. (See PRECAUTIONS and ADVERSE REACTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM (See WARNINGS)

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity There was also no mutagenic response in in vitro bacterial tests No intrinsic effect on fertility was observed in rats

Pregnancy. Category C Reproduction studies have been conducted in mice, rats, and rabbits Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality These doses, in some studies, have been reported to cause skeletal abnormalities In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women, therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus

Nursing Mothers. It is not known whether this drug is excreted in human milk Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this situation

Pediatric Use. Safety and effectiveness in children have not been established

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition In many cases, the relationship to CARDIZEM has not been established The most common occurrences, as well as their frequency of presentation, are edema (2 4%), headache (2 1%), nausea (1 9%), dizziness (1.5%), rash (1.3%), asthenia (1 2%), AV block (1.1%). In addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence.

Cardiovascular	Flushing, arrhythmia, hypotension, bradycardia, palpitations, congestive heart failure, syncope
Nervous System	Paresthesia, nervousness, somnolence, tremor, insomnia, hallucinations, and amnesia.
Gastrointestinal:	Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH
Dermatologic:	Pruritus, petechiae, urticaria, photosensitivity
Other	Polyuria, nocturia

The following additional experiences have been noted:

A patient with Prinzmetal's angina experiencing episodes of vasospastic angina developed periods of transient asymptomatic asystole approximately five hours after receiving a single 60-mg dose of CARDIZEM

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM erythema multiforme, leukopenia, and extreme elevations of alkaline phosphatase, SGOT, SGPT, LDH, and CPK. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established

OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diltiazem has been limited. Single oral doses of 300 mg of CARDIZEM have been well tolerated by healthy volunteers. In the event of overdosage or exaggerated response, appropriate supportive measures should be employed in addition to gastric lavage The following measures may be considered

Bradycardia	Administer atropine (0.60 to 1 0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously
High-Degree AV Block	Treat as for bradycardia above Fixed high-degree AV block should be treated with cardiac pacing
Cardiac Failure	Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics.
Hypotension	Vasopressors (eg, dopamine or levarterenol bitartrate).

Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating physician.

The oral/LD_{50}'s in mice and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively The intravenous LD_{50}'s in these species were 60 and 38 mg/kg, respectively The oral LD_{50} in dogs is considered to be in excess of 50 mg/kg, while lethality was seen in monkeys at 360 mg/kg The toxic dose in man is not known, but blood levels in excess of 800 ng/ml have not been associated with toxicity

DOSAGE AND ADMINISTRATION

Exertional Angina Pectoris Due to Atherosclerotic Coronary Artery Disease or Angina Pectoris at Rest Due to Coronary Artery Spasm. Dosage must be adjusted to each patient's needs Starting with 30 mg four times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four times daily) at one- to two-day intervals until optimum response is obtained Although individual patients may respond to any dosage level, the average optimum dosage range appears to be 180 to 240 mg/day There are no available data concerning dosage requirements in patients with impaired renal or hepatic function. If the drug must be used in such patients, titration should be carried out with particular caution

Concomitant Use With Other Antianginal Agents:

1. **Sublingual NTG** may be taken as required to abort acute anginal attacks during CARDIZEM therapy
2. **Prophylactic Nitrate Therapy** — CARDIZEM may be safely coadministered with short- and long-acting nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.
3 **Beta-blockers.** (See WARNINGS and PRECAUTIONS.)

HOW SUPPLIED

Cardizem 30-mg tablets are supplied in bottles of 100 (NDC 0088-1771-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1771-49) Each green tablet is engraved with MARION on one side and 1771 engraved on the other CARDIZEM 60-mg scored tablets are supplied in bottles of 100 (NDC 0088-1772-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1772-49). Each yellow tablet is engraved with MARION on one side and 1772 on the other

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Public Relations: A Powerful Marketing Tool

Art Stevens

Letter from the Editor to Dr. Charles W. Styron, Chairman of the NCMJ Editorial Board:

Dear Charles:

This is a paper written by a public relations firm hoping to make sales to North Carolina doctors. It is the best statement of the differences between commercial advertising and public relation firms that I have read. What should I do with it?

Dr. Styron's response:

Dear Gene:

The article published herewith presents the differences between overt, unacceptable advertising in medicine versus acceptable means of presenting one's attributes. For years academic centers, clinics, and individuals have "advertised" their wares through professional papers, professional presentations, media announcements of progress in medicine, new techniques, et cetera. Substantial or real progress in medicine has somehow become known to the profession and also to the news media without any effort on the part of the individual or group to make such progress known.

Now there is encouragement by government agencies to make advertising ethical and permissible to all types of professional groups. Fortunately, medicine for the most part has rejected what has been considered unethical advertising.

So today, even in acceptable presentation of medical expertise, there are differences of opinion on how far physicians should go. Some believe in quick and public announcements of what he has to offer. Others believe in time, effort, education, and availability, thus gaining public and professional acceptability the "old-fashioned way, by earning it."

This article presents the differences admirably and for this reason it is made available to our membership.

NOWHERE is change more evident in medicine today than in the tradition-shattering idea of promoting private medical practice through the standard marketing techniques of advertising and public relations.

Promotional methods now available to every medical care professional have, like medical technology itself, moved far beyond the horse-and-buggy era. Yet, almost a decade after the Supreme Court and Federal Trade Commission rulings setting aside restrictions against advertising by professionals, controversy continues unabated about such uses.

Historically, restraints on advertising were instituted to protect a medically unsophisticated public from falling prey to the unscrupulous. Even today, years after promotion became an issue, so strong is the suspicion of an alliance between advertising and purely selfish motives that its employment can still stigmatize the user.

These circumstances present the medical profession with a new challenge: to develop methods of expanding its channels of communication with an information-hungry public without transgressing reasonable ethical guidelines. The situation calls for methods which provide the public with responsible information and at the same time preserve respect for the dignity and standards of conduct of the medical profession. One such acceptable method is public relations.

Differences Between Advertising and Public Relations

While both advertising and public relations are powerful aids in helping shape public perceptions and attitudes, there are some basic differences in reader response to them.

Both advertising and public relations deal in information. While the purpose of information in advertising is to induce a desire to buy, in public relations information is used primarily to promote good will and understanding.

Space in which advertising appears is purchased; public

From Lobsenz-Stevens, Inc., 460 Park Avenue South, New York 10016.

relations space is not. Advertisers exert total control over the information they present in the purchased space and the amount of information presented is limited by cost alone. On the other hand, control of public relations information rests with the media and is presented only when it meets rigid media criteria of newsworthiness or beneficial public information. Consequently, because pr information is filtered through newscasters, reporters and editors, these third-party reports seem more objective and therefore often more believable.

Growing Public Hunger for Medical Information

Despite the fact that self-promotion efforts raise some eyebrows within medical circles and prompt discussion of appropriate ethical guidelines, the trend toward such promotion has been growing steadily for several years. This has happened because the public is eager for more medical information.

In response to this emerging public appetite, all the media have expanded their coverage of medical facts and developments. This circumstance has made it possible for farsighted medical people to utilize the situation effectively. By making it part of their professional duty and responsibility to engage in providing the public with reliable, comprehensible, up-to-date information, they enlighten the public and simultaneously promote themselves.

Public Relations Methods Vary Widely

Public relations offers a variety of opportunities to engage in this process: guest appearances on discussion shows on radio and television; "how-to" books on medical subjects; guest editorials on specific health or fitness-related topics; articles written by or quoting a medical professional; syndicated health and fitness columns; participation as speakers in local groups and meetings where issues related to medicine may be part of the agenda. Each of these activities provides a needed public service. In addition, each represents a powerful way of increasing public awareness of a specific physician and that individual's expertise. Such opportunities are having a profound influence on how professionals can build and enlarge their practices. Compared with these uses of the media, the old hanging-out-a-shingle-and-listing-oneself-in-the-yellow-pages lacks impact. And waiting for word-of-mouth referrals takes many years.

What to Expect From Public Relations

Responsible pr professionals have guidelines which enable them to help medical specialists market themselves honestly. If you use public relations help, you can rightly expect the following:

1. Your name before a wide public. Public relations can achieve enhanced recognition quickly and associate your name with a specific set of skills.
2. Public awareness of your viewpoint, outlook, expertise.
3. A balanced campaign employing national, regional and local exposure, as appropriate to your objectives.
4. A systematic campaign with a timetable, written plan, set of themes for articles, scheduled interviews and regular progress reports. These make it possible to monitor results.
5. Ongoing interaction with your agency.
6. Identified objectives well suited to your marketing needs. These needs will vary as specialties themselves vary. For example, if the specialty is otolaryngology, the pr campaign might include:

- An article in a national consumer publication, such as *The Saturday Evening Post*, on "Hearing Impairment: Who Is At Risk?"
- An article in a national consumer publication, such as *Time* or *Business Week*, on "How to Counter Negative Public Attitudes Toward Hearing Loss."
- Appearances on TV programs — national or local — to discuss latest diagnostic and surgical procedures in hearing loss treatment.
- Releases to health/medical editors of national women's, men's and general interest magazines, large circulation daily newspapers and news syndicates on treating hearing loss.
- Speaking engagements to reach specific regional groups dealing with hearing loss: the elderly, high risk groups in industry, etc.

These examples illustrate how a pr campaign can reach a national audience, a specific local group or both. It can gain attention, educate, alert, inform — and achieve these tasks effectively and responsibly.

Health care providers employing public relations can expect to become much better known and to be sought after by people who are in need of the precise medical services they provide. Moreover, these activities can bring honor, recognition and credit both to themselves and to their colleagues. At the same time the entire marketing effort can be accomplished in an ethical, dignified, professional manner.

LEARNING WITHOUT WORDS

What I Needed to Know About Cyclosporine

James T. C. Li, M.D., Ph.D.

• *How effective an immunosuppressant is cyclosporine? This article reviews its pharmacology and mechanisms, effectiveness and side effects in clinical studies performed over the last several years.*

I recently had occasion to take care of a patient who had been on cyclosporine immunosuppression following a bone marrow transplant. Not knowing much about cyclosporine, I went to the library to find a review article to read. Was cyclosporine the ideal immunosuppressant? Was it effective in all types of transplantations? What were the side effects?

There were abundant reports on pharmacokinetics, putative mechanisms of action, and several reports of clinical trials but no single paper reviewing all relevant aspects. This brief report contains the salient points distilled from more than 50 articles on cyclosporine. The information should be useful to any physician who has a patient taking cyclosporine.

Cyclosporine is a new immunosuppressive agent recently approved for general clinical use by the FDA. The introduction of this new drug has been enthusiastically received by physicians involved in clinical transplantation. Cyclosporine has proved to be equal or superior to conventional immunosuppressive therapy in terms of both patient survival and graft survival in all studies. Liver and heart allograft recipients in particular have greatly benefited from cyclosporine immunosuppression. All this without myelosuppression and with reduced doses of corticosteroids!

Unfortunately, cyclosporine is also nephrotoxic. Pilot studies in renal transplant recipients revealed frequent post-transplant oliguria, acute tubular necrosis, and graft failure, but this high degree of nephrotoxicity now can largely be avoided by carefully adjusting doses. A recently developed radioimmunoassay capable of easily measuring cyclosporine dosing levels may decrease clinical nephrotoxicity further still.

The preliminary reports of several randomized, prospective trials in renal and bone marrow transplantation have recently been published. The collective data suggest that cyclosporine is equal, but not clearly superior, to conventional immunosuppressive therapy in these two applications.

Pharmacology

The cyclosporines are cyclic peptides extracted from soil fungi. Cyclosporine A is extracted from the soil fungus *Tolypocladium inflatum*. Biological screening showed this compound to have potent immunosuppressive properties without myelotoxicity, and subsequent animal studies demonstrated the effectiveness of cyclosporine A in transplantation. Presently, as the only one of the cyclosporines approved for clinical use, it is called simply cyclosporine.

Cyclosporine consists of 11 aliphatic aminoacids. This accounts for the hydrophobic nature and poor water solubility of the drug. Because of these properties, cyclosporine is administered orally in an olive-oil based solution; it can also be administered intramuscularly or intravenously. Following an oral dose, peak blood levels are detected in 2-3 hours. Bioavailability varies between 20 and 50 percent.

Cyclosporine is metabolized primarily through the liver with less than 6 percent excretion in the urine. Various metabolites of cyclosporine have been identified in humans but their immunosuppressive properties are not known. The study of a renal transplant recipient who required an ileostomy demonstrated biliary excretion and probable enterohepatic recirculation of cyclosporine and its metabolites.

The terminal half-life of cyclosporine has been estimated at 14-17 hours. Factors complicating precise pharmacokinetic measurement of serum half-life include the distribution of the drug into body tissues and the aforementioned enterohepatic circulation. Cyclosporine is usually administered orally as a single daily dose.

Clinical Studies

A number of large, well-designed, randomized prospective studies are going on that compare cyclosporine with conventional therapy. The experience in renal transplantation is by far the most extensive.

The results of a European Multicenter Trial comparing cyclosporine with azathioprine and steroids in renal allograft recipients show estimated six-month graft survival probabilities of 73 percent and 53 percent, respectively.[1] Similarly, the Canadian Multicenter Transplant Study Group compared cyclosporine and prednisone with conventional therapy in cadaveric renal transplantation. Both graft survival (80.4% vs 64%) and patient survival (91.1% vs 89%) improved in the cyclosporine group.[2]

On the other hand, prospective trials at the University of Minnesota and University of Sydney, Australia, showed excellent but equivalent success in the cyclosporine and control groups when patient and graft survival was com-

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pared. The cyclosporine groups in these trials manifested some benefit in terms of fewer readmissions, fewer acute rejection episodes, lower hospital costs, fewer steroid side effects, and decreased myelotoxicity. It is not yet known whether the combination of cyclosporine and steroids is superior to cyclosporine alone.

A number of conclusions can be drawn from this widespread experience. Renal function in the cyclosporine groups averages 10-20 percent lower than in control groups, but this degree of renal insufficiency remains stable over time. Merion and colleagues have followed cyclosporine renal transplant recipients for up to 4½ years and have not observed progressive deterioration of renal function. It is not known whether careful monitoring of serum cyclosporine levels by radioimmunoassay can reduce cyclosporine nephrotoxicity.

The high incidence of lymphomas in pilot studies has not been confirmed by later studies. Lymphoproliferative disorders probably occur in 1-2 percent of cyclosporine-treated patients, similar to conventional immunosuppression. Bacterial infections in renal transplant recipients also appear to be equivalent in cyclosporine and control groups, while fewer CMV infections may occur in cyclosporine-treated patients. Heart transplant recipients treated with cyclosporine clearly exhibited a lower mortality from infectious causes (8% vs 40%). Other major effects of cyclosporine include hepatotoxicity, gingival hypertrophy, hirsutism, and tremor.

Initial reports suggested that cyclosporine was superior to conventional therapy in bone marrow recipients as well. The enthusiasm dampened, however, when the preliminary results of two ongoing randomized prospective trials showed no significant difference between the two groups in terms of both patient survival and graft-versus-host disease. As with all preliminary reports, no firm conclusions should be drawn until these and other controlled studies are completed.

Cyclosporine has greatly improved success in liver transplantation. The success has been so impressive that it is highly unlikely that a randomized trial will ever be performed. The University of Pittsburgh reports that 42 of 67 consecutive liver transplant recipients survived 1 year or more (63%).[3] This compares favorably with a 33 percent one-year survival in the pre-cyclosporine era.

Similarly, cyclosporine has significantly lowered mortality in heart transplant recipients. At Stanford, overall mortality has dropped from 62 percent to 21 percent since the introduction of cyclosporine immunosuppression. However, two adverse effects of cyclosporine have been observed in heart transplant recipients: 1) hypertension develops in most patients; 2) myocardial fibrosis has been detected by biopsy or postmortem examination. Present information suggests that this fibrosis is not progressive and does not lead to hemodynamic compromise, but further study is needed to fully assess its long-term significance. The role of cyclosporine in transplantation is summarized in table 1.

Last but not least is the experience in heart-lung transplantation. This dramatic operation is performed in patients with end-stage pulmonary hypertension. Before cyclosporine immunosuppression was introduced, survival was measured in days. Jamieson and co-workers have recently reported their experience with 13 heart-lung transplant recipients, all of whom received cyclosporine as part of their immunosuppressive regimen.[4] Ten patients were alive at the time of publication, four patients having survived more than 12 months and one patient alive after two years. Cyclosporine has certainly made a significant impact in this field!

Mechanism

Although the mechanism of action of cyclosporine has not been fully elucidated, recent data demonstrate that cyclosporine interferes with T-cell activation (reviewed in 5). These studies show that cyclosporine inhibits the production of Interleukin II. This factor is produced by helper T-cells and is essential for cytotoxic T-cell activation and proliferation. Other proposed mechanisms of cyclosporine immunosuppression include the suppression of interferon production, the facilitation of tolerance induction, and the generation of suppressor cells. The effects of cyclosporine at the molecular level are unknown.

Conclusions

Cyclosporine is an effective immunosuppressant which is superior to previous therapy in heart and liver transplantation and at least equal in effectiveness in renal and bone marrow transplantation. Nephrotoxicity remains an important problem and may limit its overall applicability. The incidence of drug-induced lymphomas appears similar to that of conventional immunosuppressive therapy. As the mechanism of T-cell activation unravels, other inhibitors of T-cell function may well be developed. One can expect these new immunosuppressive agents to be utilized in applications beyond clinical transplantation.

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Table 1.

Cyclosporine Compared with Conventional Immunosuppression

Donor Organ	Efficacy
Kidney	Equal or Superior
Bone Marrow	Equal
Liver	Superior
Heart	Superior
Heart-Lung	Superior

PHARMACOTHERAPY

Clinical Uses of Anti-Thymocyte Globulin (ATGAM), Part II

Colleen Gilbert

Aplastic Anemia

ATGAM is currently undergoing active investigation for therapeutic efficacy in the treatment of aplastic anemia.[15, 20, 21, 36, 37] Aplastic anemia is an often fatal disease of bone marrow suppression in which there is inadequate production of erythrocytes, as well as granulocytes and platelets in severe cases.[36, 38] An immunological component has been postulated to be involved in the pathogenic mechanism of this disease. The humoral or cellular immunity may be involved by inhibition of stem cell development or lack of hematopoietic cofactors. Bone marrow transplant is the therapy of choice if a suitable donor can be found. Unfortunately, this is often not possible and various medical treatments have been used, including androgens, steroids, cyclophosphamide, and ATG. ATG may work by decreasing the number of T suppressor cells that may be acting on the hematopoietic stem cells, or it may alter the release of soluble factors which may be involved in the pathogenesis of aplastic anemia.[36] Several studies have been published which evaluate ATGAM therapy in aplastic anemia. There is at least one multicenter trial in progress in which Duke is participating.

Preliminary trials of ATGAM for severe aplastic anemia involved a small number of patients and used ATG only in conjunction with other agents such as steroids and androgens. Approximately 50% of patients responded to ATG given 10-15 mg/kg over 10-14 days.[15, 18, 37] Champlin et al evaluated ATGAM for moderate to severe aplastic anemia in a prospective, randomized trial.[21] They demonstrated a substantial benefit from ATG given 20 mg/kg/day for eight days. Patients were premedicated with acetaminophen and diphenhydramine 30 minutes prior to infusion and 25-50 mg hydrocortisone was used to control chills and urticaria. A total of 42 patients was enrolled in the study and the 21 controls received supportive care only. After three months, 12 of the control patients also received ATG so that a total of 33 patients was treated, of which 19 responded to ATGAM therapy. Response to ATGAM was defined as elimination of transfusion requirements or only occasional platelets required. All patients exhibited some symptoms of serum sickness in 6-18 days of ATG therapy, which was controlled by prednisone 40 mg/m^2 tapered over two weeks. Champlin recommended initiation of ATGAM therapy within four months of disease diagnosis, since there appears to be an inverse relationship between positive ATG response and duration of aplasia.

Bone Marrow Transplantation and Graft-vs-Host Disease

Anti-thymocyte globulin has been considered for immunosuppressive adjunctive therapy for bone marrow transplantation, prophylaxis for graft rejection or the development of graft-versus-host disease (GVHD). GVHD is a major complication of bone marrow transplantation. It occurs in 30-50% of marrow graft recipients despite HLA matching and immunosuppression.[24] Basically, it is a reaction of donor lymphocytes against the recipient which can take many forms. Manifestations of GVH disease may include debilitating skin disease, severe oral and esophageal mucositis, malabsorption, pulmonary insufficiency, liver disease and recurrent bacterial infections.[26]

Speck et al have used a Swiss equine ATG in conjunction with bone marrow transplantation.[19] They compared results of three groups: Group A (n = 18) — HLA matched sibling bone marrow graft plus cyclophosphamide 50 mg/kg x four days — 44% survival; Group B (n = 20) — LRD graft plus ATG 40 mg/kg x four days plus norethandrolone — 74% survival; and Group C (n = 12) — ATG 40 mg/kg x four days plus norethandrolone, no donor — 67% survival. There was no GVH disease in group B, while group A experienced six deaths due to GVHD and two survivors have chronic GVHD.

Ramsey et al conducted a randomized trial to compare two regimens in the prevention of acute graft-versus-host disease.[25] Patients were all recipients of HLA matched sibling bone marrow and were being treated for aplastic anemia or leukemia. Prophylaxis of GVHD has included methotrexate post-transplantation therapy, *in vitro* treatment of donor marrow with anti-T cell globulin, and immunosuppression with cyclosporine or ATG after transplantation. In this study, 35 patients were given methotrexate (MTX) 15 mg/m^2 IV one day post-transplantation, then 10 mg/m^2 on days 3, 6, and 11, followed by weekly injections up to 100 days. Another 32 patients received the same methotrexate regimen plus 15 mg/kg ATG QOD for seven doses beginning on day 8 and oral prednisone 40 mg/m^2 on days 8-20. A total of 48% of the MTX group developed some manifestations of GVHD, while only 21% of the MTX, ATG and prednisone group developed GVHD. The ATG used in this study was prepared at the University of Minnesota.

Another preliminary trial of prophylaxis and treatment of

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GVHD with ATGAM was conducted in Seattle by Weiden et al.[39] Eligible patients received HLA matched sibling bone marrow for treatment of hematologic malignancies and had not received any ATG previously. All patients received MTX post-transplantation according to the regimen described previously. When definite evidence of early engraftment was seen, 17 patients were randomized to receive prophylactic ATG and 12 patients were randomized as controls. Ultimately, 12 patients were given ATG, 7 mg/kg QOD for six doses beginning one to four weeks post-transplantation. The patient population was small but did indicate some benefit from using ATG. GVHD developed in three of 12 ATG patients and in six of 12 control patients. This group also used the same low dose ATG to treat nine patients for GVHD. Control patients ($n = 6$) were treated with prednisolone for 10 days. Results were not conclusive, due to the small patient population. However, both ATG and steroids resulted in improvement of GVHD in most patients. This same group of investigators went on to conduct a randomized trial comparing ATG and corticosteroids in the treatment of GVHD in allogeneic marrow graft recipients.[24] The conditions and ATG dosage were the same as previously described. Patients who could not tolerate IV equine serum were given rabbit ATG intramuscularly. The study looked at 20 patients receiving steroids and 17 patients receiving ATG. No significant differences were noted between the two regimens in the primary treatment of acute GVHD.

Other Uses

Anti-thymocyte globulin has been considered as adjunctive therapy in a variety of other disease states. Due to ATG's effect of temporarily but significantly reducing circulating T cells, it has been used in non-Hodgkins lymphomas, Sezary syndrome and T-cell leukemias.[22, 23] Studies to date are small and inconclusive. Thus far, long-term beneficial effects have not been documented. Immunosuppression, including ATG, has not been demonstrated to be superior to placebo in the therapy of multiple sclerosis.[27] There have been some promising results in the treatment of another autoimmune disease, myasthenia gravis. Pirofsky noted some response in eight of 10 patients treated with low dose daily ATG.[28, 29] Larger, well controlled studies will be needed to substantiate this preliminary work. Finally, ATG has been used in a small number of severely burned patients in conjunction with skin allografting.[3, 14] ATGAM was preferred to azathioprine by this Harvard group, due to the more prolonged, non-specific marrow suppression seen with azathioprine. This group uniquely controlled ATGAM dosage by monitoring degree of T-rosette inhibition.

Clinical Toxicity, Prevention and Management

The fundamental nature of ATGAM is that of a foreign horse protein. As such, ATG has a high potential to stimulate immunogenic responses in the human host. Early side effects which were expected and have been documented include chills, fever, erythema, pruritis, serum sickness and anaphylaxis. Chills and fever are most common and occur in one third of all patients.[2] The incidence of anaphylaxis is low ($<1\%$), although ATG skin testing is always performed before administration.[2] Widely disparate reports of serum sickness occurrence are apparently related to the degree of concurrent immunosuppression and the use of corticosteroids. The incidence of this problem in renal allograft recipients is less than 1%; however, in therapy of aplastic anemia some symptoms of serum sickness occur in virtually all patients at about day 8-16.[20]

Other important early side effects include leukopenia (14%), thrombocytopenia (11%), erythema and pruritis (12.5%), local phlebitis (12.5%) and hemolysis ($<1\%$).[2] Thrombocytopenia is thought to be due to the presence of anti-platelet antibodies in the ATG, because of the common surface antigens of platelets and thymocytes.[40] This causes platelet aggregation and, in the presence of complement, lysis (although complement is not necessary for the anti-platelet effect).[40]

Serious, delayed toxicity has been feared with the use of this agent. Actually, there has been no significant increase in neoplasias, mortality, anti-glomerular basement membrane injury, or aseptic necrosis.[2] Some increase in sepsis by viral or fungal agents has been reported but this is no different from that seen with high dose steroids and azathioprine.[35]

Before administering ATG a skin test must be performed. An intradermal injection of 0.1 ml of a 1:1000 dilution in normal saline is given with a saline control.[2] Caution should be used if a wheal, erythema, itching or local swelling occur. ATGAM is contraindicated if a generalized rash, tachycardia, dyspnea, hypotension or anaphylaxis occur. It is important to realize that an allergic reaction may still occur from ATG therapy despite a negative skin test. Privately produced goat and rabbit anti-thymocyte globulin is available in this country for patients who cannot tolerate equine serum. Patients should, of course, be skin tested before these preparations are utilized.

The recommended dosing regimen for ATGAM is 10-15 mg/kg/day for 14 days, then QOD for 14 days.[2] Begin administration within 24 hours of renal transplant or when allograft rejection is diagnosed. Dosage for investigational uses is not clearly defined, although this regimen is similar to protocols using ATGAM for aplastic anemia. ATGAM must be diluted to 1 mg/ml in 0.45% or 0.9% saline solutions. The total time during which the product is diluted should not exceed 12 hours, including administration time. Infuse slowly, over 4-8 hours, through a central line (preferably with an in-line filter). This will help minimize phlebitis and thrombosis. Do not mix ATGAM with 5% dextrose, as low salt concentrations cause precipitation of drug.[2] Also, avoid highly acidic solutions which are incompatible with ATGAM.[2]

In order to minimize many of the early side effects of ATG, patients may be premedicated with acetaminophen and diphenhydramine. Hydrocortisone (50 mg) or methylprednisolone (40 mg/m^2) may be administered during ATG infusions. In addition, prednisone 5-20 mg QID is recommended throughout ATG therapy.[2] Immediately halt ATGAM therapy if any anaphylactic-type reaction occurs and administer 0.3 ml aqueous epinephrine (1:1000) intramuscularly. Provide appropriate resuscitative measures and do not resume ATG.[2] ATGAM is available in 5 ml vials containing 250 mg equine globulin stabilized in 0.3 M glycine and preserved with 0.01% thimerosal. The acquisition cost is $87.50/5 ml vial.

Summary

Anti-thymocyte globulin has undergone extensive evaluation as an immunosuppressive agent in clinical transplantation and autoimmune disease. Its benefit has been established in prophylaxis and treatment of renal allograft rejection. Results are promising in investigational study of ATGAM for aplastic anemia. *In vitro* and *in vivo* assays, currently used to define ATGAM activity, have not clearly correlated with clinical efficacy. Development of more predictive assays and monitoring criteria will certainly improve the utilization of ATG. In the future, improved production of specific anti-T cell serum will continue with the use of hybridoma techniques to develop monoclonal antibodies.[41] Anti-thymocyte globulin is a valuable immunosuppressive agent used alone or in conjunction with other agents such as azathioprine and corticosteroids. Future studies will further define the role of this agent in various disease states and should provide some interesting clinical comparisons with other new drugs such as cyclosporine.[30]

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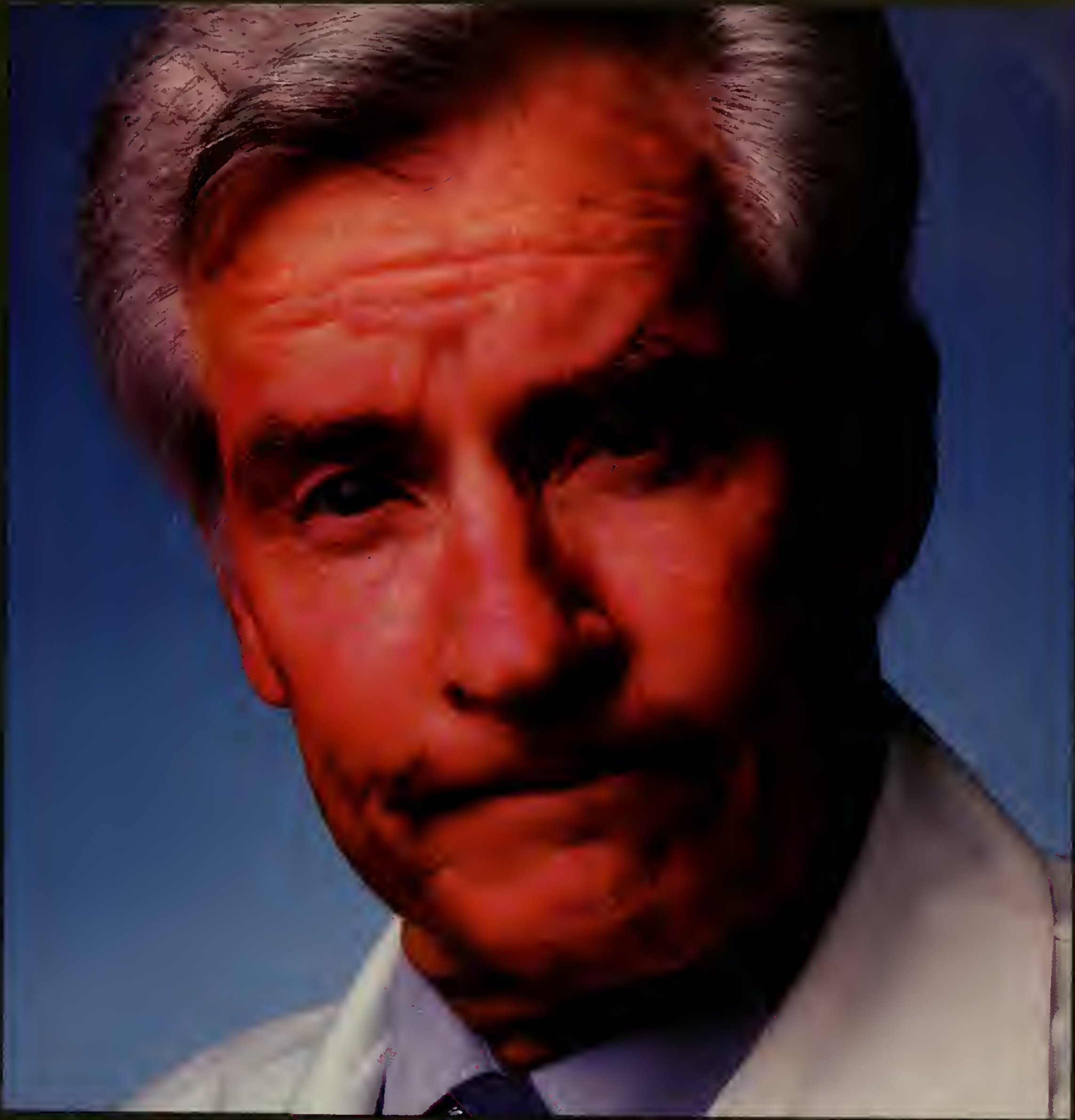

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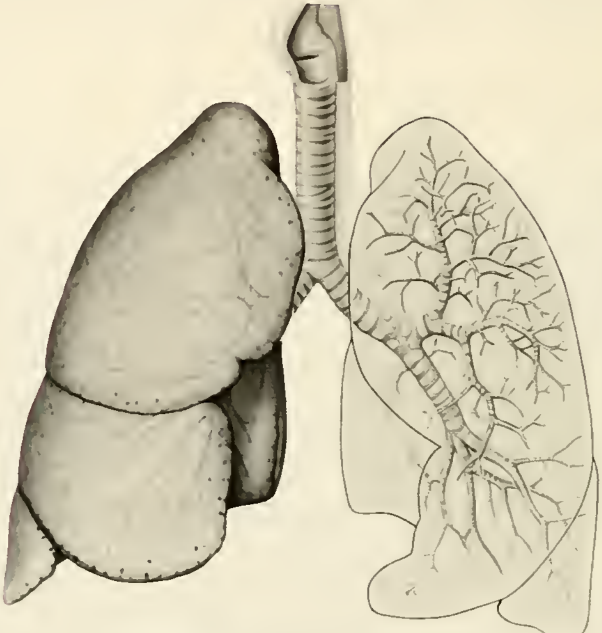

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Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

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Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy – *Pregnancy Category B* – Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor® (cefaclor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers – Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor is administered to a nursing woman.

Usage in Children – Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions. Adverse effects considered related to therapy with Ceclor are uncommon and are listed below.

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain – Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic – Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic – Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal – Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[061782R]

Note: Ceclor® (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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North Carolina Medical Journal

Features for Patients December 1984

Bulimia and Anorexia Nervosa: Dangerous Eating Disorders

Robert T. Harris, M.D.

Eating and proper nutrition are obviously essential to maintain good health. Just like so many other activities that we humans indulge in, however, eating can become a problem if it is done too little or too much. Eating can also become a problem if the substances eaten are harmful or if eating is combined with other potentially harmful activities, like self-induced vomiting. The American Psychiatric Association has defined four eating disorders: bulimia, anorexia nervosa, pica, and rumination disorder.[1]

Eating disorders are becoming more commonly recognized. A recent survey of 300 suburban women shoppers found bulimia in 10%, anorexia nervosa in 1%.[2] On college campuses, surveys have detected bulimia in up to 19% of women and 5% of men.[3] Recent revelations in newspaper, magazine, and television reports of eating disorders affecting certain celebrities (e.g., Cheri Boone, Karen Carpenter and Kathy Rigby McCoy) have brought eating disorders to the public's attention.

Though this article focuses on bulimia, anorexia nervosa is discussed briefly and the two disorders are contrasted. These two disorders share certain features but differ on several points as well (see table 1). Pica — the ingestion of non-nutritive substances like paint, plaster, or clay — and rumination disorder — chronic, involuntary regurgitation of nutritive substances (primarily affecting infants) — are much rarer eating disorders and are not dealt with here. On the other hand, obesity is not an eating disorder but a physical condition that usually results from poor eating/nutritional habits and lack of exercise.

Features and Causes of Bulimia

Known alternately as bulimarexia, bulimia nervosa, or the binge-purge syndrome, bulimia is likely the most common eating disorder, although it has been less studied than anorexia nervosa. It is characterized by the episodic but rapid ingestion of large quantities of food in short periods of time. Typically, the patient consumes high-caloric, easily ingested and easily regurgitated foods: a one-half gallon carton of ice cream and/or a full bag of cookies eaten in 30 to 40 minutes is not unusual. The patient then "purges" her/himself by inducing vomiting and then resumes the binge with additional foodstuffs. The entire episode of cyclic binges and purges may continue for several hours. An episode may end with the patient feeling exhausted and falling asleep or with the onset of unpleasant physical sensations, like abdominal pain or sore throat. Alternatively, the episode may be interrupted by some social contact such as someone walking in on the patient in the middle of an episode. Ending an episode in this way is particularly troublesome to bulimic patients, as they strive to conceal their behavior (and "evidence," like large quantities of food) from family and friends.

Bulimic episodes may occur daily (or even more than once daily) or several times a week. A period in which bulimic episodes occur frequently is typically followed by a period of infrequent episodes, or even normal eating behavior, only to have bulimia return days or weeks later. Its episodic nature has prompted the comparison of bulimia and alcoholism. Indeed, the two disorders have several common features:

1. they involve the episodic overindulgence of a substance regarded as normal (or with alcohol, at least socially acceptable) when consumed in moderation;
2. the overindulgence tends to be done in secrecy and the reported amount (of food or alcohol) consumed is minimized;
3. patients are plagued by extreme guilt and feelings of being "out of control" of their behavior;
4. the binges are typically followed by periods of abstinence, only to

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have the overindulgent behavior return in days or weeks;

5. the disorders may be attended by profound depression, which may be expressed by the overindulgent behavior;
6. the disorders carry the potential for a variety of significant, even lethal, medical complications.[4]

A difference between alcoholism and bulimia is that alcoholism is usually regarded as a disorder affecting men (though the prevalence in women is likely higher than generally regarded) whereas bulimia, like anorexia nervosa, appears to be a disorder much more commonly affecting women. Female victims of both disorders have reported that their bulimia was much more difficult to cure than their alcoholism, thus underscoring the gender selectivity of the two disorders. Thus, bulimia and alcoholism can be thought of as sex-specific expressions of a single indulgence disorder.

Bulimia appears to share a socioeconomic feature with anorexia nervosa: both eating disorders are almost exclusively found in white women from the middle to the upper socioeconomic classes. Another feature shared by both disorders is the "fear of fatness" commonly expressed by bulimic and anorexic patients. A clue to understanding the occurrence of bulimia and anorexia nervosa may be found in epidemiologic data which show that as socioeconomic status and age (beyond the adolescent years) increase the incidence of obesity decreases among women.[5] The prevalence of obesity is greatest among black women whose family income is below the national poverty level. Both bulimia and anorexia nervosa are exceedingly rare among black women, especially those from lower income families, where obesity is more "the norm" for women, with 49% of poverty-level black women being obese.[5]

The "fear of fatness" found in bulimic and anorexic women may be appreciated better if one considers the women who have been established as models of great beauty, charm, and poise. Over the past fifty years, the winners of the Miss America pageant have become taller while their body weight has decreased on average. The same phenomenon is observed in the *Playboy* magazine centerfold models, many of whom weigh less than the calculated ideal body weight for their height. Yet none of these "model" women are anorexic in appearance, as being too thin is generally regarded as unattractive as being too fat.

Bulimia may seem to be the perfect answer for women who fear "gaining an ounce of fat" yet want to remain "normal" in appearance. Many bulimic women have found that they can eat all they want without gaining weight. Indeed, the majority of bulimic women are near their ideal body weight and some are even heavier. This is in sharp contrast to anorexic patients who by definition are at least 25% below their normal weights. Furthermore, anorexic patients take great pride in their thinness and their ability to shun food so consistently (though some anorexic patients may occasionally binge and purge).

The extreme weight consciousness and "fear of fatness" shared by bulimic and anorexic patients seems consistent with the fact that nearly 50% of bulimic women have a history of anorexia nervosa.[6] Thus bulimia may develop as a "burned-out" form of anorexia nervosa in patients with an anorexic history. Bulimia "allows" these women to maintain their weight consciousness while not appearing anorexic. Bulimia in a previously anorexic woman is viewed as a bad prognostic sign, with bulimia becoming a chronic problem which may continue for many years.

Purging behavior in bulimic patients most commonly takes the form of self-induced vomiting. However, bulimic patients have found other clever ways of purging themselves of the foodstuffs and guilt imposed by their binge eating. Abuse of laxative or diuretic drugs and excessive physical exercise are used by some bulimic patients to rid themselves of unwanted calories. Most bulimic patients are unaware, however, that laxatives and diuretics are ineffectual in disposing of unwanted calories.[7] Furthermore, when taken frequently or in large quantities (some patients may take up to 50 laxative tablets a day), these drugs can present dangerous medical problems. Hypokalemia, or lowered potassium content in the blood, is a common result of laxative and diuretic abuse. Symptoms ranging from mild muscle cramps and weakness to fatal cardiac arrhythmias (heart beat irregularities) may result from hypokalemia.

A number of other medical problems can result from binge eating and self-induced vomiting,[4] even if laxatives or diuretics are not used. Acute dilatation (rapid expansion) and even rupture of the stomach have followed large binges. Heart failure has developed in patients who suddenly embark on a series of binges after a period of self-imposed starvation. Aspiration pneumonia, rupture of the esophagus, hypokalemia and other metabolic derangements may follow frequent vomiting (some patients induce vomiting 35 to 40 times a day). Even the teeth are not spared, as frequent vomiting erodes the protective enamel of teeth.

Treatment Considerations

Treatment of bulimia begins with the patient wanting help and accepting the fact that her behavior is abnormal and dangerous. Again, one is reminded of alcoholism; treatment of the alcoholic patient is almost impossible until he wants help. Bulimic patients, like alcoholics, may feel such profound guilt for their behavior that "admitting" it to anyone may be an obstacle to treatment. Family members, ministers, teachers, friends, or primary care physicians (rarely psychiatrists initially) may be approached by the bulimic patient. A

Table 1. Comparison of Bulimia and Anorexia Nervosa

	Bulimia	Anorexia Nervosa
Age of Onset	Late adolescence through young adulthood	Usually mid- to late adolescence
Body weight	Variable; near ideal body weight but may be above or below	25% less than normal weight for height
Self-imposed starvation	Seldom a feature	Always a feature
Fears of fatness	Commonly	Always
Disorder concealed from discovery	Always a feature	Rarely a feature; patients take pride in their thinness and ability to shun food
Binge-purge behavior	Always a feature	Occasionally a feature
Medical complications (see text for definitions)	Hypokalemia, parotid enlargement, aspiration pneumonia, esophageal tears, gastric dilatation, dental erosions	Protein-calorie malnutrition, amenorrhea, anemia, bradycardia (slow heart rate), infertility, lanugo (downy hair), heart failure, sleep disorder

sympathetic, non-judgmental attitude by the one approached will facilitate the treatment process by allowing the patient to feel that she has a supportive ally.

The woman must then be referred for evaluation (medically and psychologically), and specific treatment of the eating disorder must begin. Primary care physicians may be the ones to make the diagnosis, possibly even before the patient admits the abnormal behavior. Non-specific complaints of weakness, abdominal discomfort or fatigue may lead the physician to certain physical findings on examination (e.g., parotid gland enlargement or muscle tenderness or weakness) or certain laboratory abnormalities (e.g., hypokalemia) which suggest the diagnosis. Further medical evaluation may be necessary to exclude the presence of other potentially dangerous medical complications of bulimia. The physician should not only treat any medical complications but also be willing to work collaboratively with the therapist treating the abnormal behavior.

Specific treatment of bulimia generally requires a mental health professional (counselor, social worker, psychologist, psychiatric nurse, pastoral counselor, or psychiatrist) with training in treating eating disorders. Behavioral treatment programs may take the form of individual or group therapy and may take place on an inpatient or outpatient basis. In-hospital treatment is necessary if significant medical problems exist or if the patient is profoundly depressed.

Behavioral assessment and treatment of bulimia begins with a baseline study. This consists of asking the patient to keep a diary of her binge-purge behavior. Data to record include the time of occurrence and length of bulimic episodes, the type and quantity of foods ingested, the frequency and methods of self-induced vomiting, the frequency, duration, and type of exercise, the frequency of laxative or diuretic drug use and how the episode ended. The patient is also asked to record her feelings at each point during the bulimic episode, any ideas as to what (if anything) may have triggered an episode and any unusual physical sensations or symptoms during or after the episode. Occasionally patients may find that the mere recording of these data is therapeutic in that it points out the severity of the problem and the need for help.

Further behavioral therapy is aimed at decreasing the frequency of bulimic episodes by imposing an undesirable condition into the episode. For example, the spontaneity and reflex nature of an episode may be countered by planning an episode; such a plan may specify the exact time, length, and place of the bulimic episode, the quantity and types of food to be ingested, and the number of vomiting episodes. The planned binge-purge episode must be carried out exactly as "prescribed" and regardless of whether the patient "feels like it." Another planned episode may be designed to occur in front of a friend or family member, thus removing the secrecy component of bulimia.

Nutritional assessment and education are often included in a treatment program. Bulimic patients may carry a variety of erroneous facts about certain foods with regard to fat or calorie content. A dietician can help design a diet that is nutritionally sound yet respects the patient's continued fear of gaining excess weight. Nutritional counsel can also provide guidelines for food preparation techniques and for handling potentially troubling situations such as shopping or eating at restaurants.

Bulimic patients frequently require psychotherapy which can be combined with behavior therapy by skilled therapists. Psychotherapy helps the patient gain an understanding of how stressful situations may result in bulimic episodes. Psychotherapy may also be needed to treat coexistent depression. Bulimia is considered by some researchers to be a "depressive equivalent" or an atypical expression of depression manifested by the eating disorder.

Indeed, depression has been diagnosed by psychiatric interview and psychological tests in a good percentage of bulimic patients. Thus one proposed treatment of bulimia is to treat the underlying depression. Psychotherapy has been employed along with antidepressant medications to treat depression. Initial studies of the use of antidepressants are promising,[8] but more study is needed to determine if these drugs provide long-term benefit in bulimia.

Referral sources for the evaluation and treatment of eating disorders, particularly bulimia, may be difficult to locate. Primary care physicians, community mental health centers, family counseling services, practicing counselors, psychologists, or psychiatrists may be local sources to check for evaluation and treatment services. Those patients without local professionals providing treatment for bulimia may wish to contact similar resources in a neighboring, larger county or may contact one of the academic medical centers which generally have physicians and behavior therapists interested in eating disorders. If all of the above fail, one of the following agencies may provide a further list of treatment resources: American Anorexia/Bulimia Association, phone 201/836-1800; Anorexia Nervosa and Associated Disorders, Inc., phone 312/831-3438.

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Warnings: Peptic ulceration and GI bleeding, sometimes severe, have been reported Ulceration, perforation and bleeding may end fatally An association has not been established Use *Motrin* Tablets under close supervision in patients with a history of upper gastrointestinal tract disease, after consulting ADVERSE REACTIONS In patients with active peptic ulcer and active rheumatoid arthritis, try nonulcerogenic drugs, such as gold If *Motrin* Tablets are used, observe the patient closely for signs of ulcer perforation or GI bleeding

Chronic studies in rats and monkeys have shown mild renal toxicity with papillary edema and necrosis Renal papillary necrosis has rarely been shown in humans treated with *Motrin* Tablets

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Fluid retention and edema have been associated with *Motrin* Tablets, use with caution in patients with a history of cardiac decompensation or hypertension In patients with renal impairment, reduced dosage may be necessary Prospective studies of *Motrin* Tablets safety in patients with chronic renal failure have not been done

Motrin Tablets can inhibit **platelet aggregation** and prolong bleeding time. Use with caution in persons with intrinsic coagulation defects and on anticoagulant therapy

Patients should report signs or symptoms of **gastrointestinal ulceration** or bleeding skin rash, weight gain, or edema

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As with other nonsteroidal anti-inflammatory drugs, borderline elevations of liver tests may occur in up to 15% of patients These abnormalities may progress, may remain essentially unchanged, or may be transient with continued therapy Meaningful elevations of SGPT or SGOT (AST) occurred in controlled clinical trials in less than 1% of patients Severe hepatic reactions, including jaundice and cases of fatal hepatitis, have been reported with ibuprofen as with other nonsteroidal anti-inflammatory drugs. If liver disease develops or if systemic manifestations occur (e g eosinophilia, rash, etc), *Motrin* should be discontinued

Drug interactions. *Aspirin*. used concomitantly may decrease *Motrin* blood levels

Coumarin. bleeding has been reported in patients taking *Motrin* and coumarin

Pregnancy and nursing mothers: *Motrin* should not be taken during pregnancy or by nursing mothers

Adverse Reactions: The most frequent type of adverse reaction occurring with *Motrin* is gastrointestinal of which one or more occurred in 4% to 16% of the patients

Incidence Greater than 1% (but less than 3%)—Probable Causal Relationship

Gastrointestinal: Nausea,* epigastric pain,* heartburn,* diarrhea, abdominal distress, nausea and vomiting, indigestion, constipation, abdominal cramps or pain, fullness of GI tract (bloating and flatulence); **Central Nervous System:** Dizziness,* headache, nervousness **Dermatologic:** Rash* (including maculopapular type), pruritus; **Special Senses:** Tinnitus, **Metabolic/Endocrine:** Decreased appetite, **Cardiovascular:** Edema, fluid retention (generally responds promptly to drug discontinuation, see PRECAUTIONS)

Incidence less than 1%—Probable Causal Relationship**

Gastrointestinal: Gastric or duodenal ulcer with bleeding and/or perforation, gastrointestinal hemorrhage melena gastritis, hepatitis, jaundice abnormal liver function tests, **Central Nervous System:** Depression, insomnia, confusion, emotional lability, somnolence, aseptic meningitis with fever and coma, **Dermatologic:** Vesiculobullous eruptions, urticaria, erythema multiforme, Stevens-Johnson syndrome, alopecia, **Special Senses:** Hearing loss, amblyopia (blurred and/or diminished vision, scotomata, and/or changes in color vision) (see PRECAUTIONS); **Hematologic:** Neutropenia, agranulocytosis, aplastic anemia, hemolytic anemia (sometimes Coombs positive), thrombocytopenia with or without purpura, eosinophilia, decreases in hemoglobin and hematocrit, **Cardiovascular:** Congestive heart failure in patients with marginal cardiac function, elevated blood pressure, palpitations, **Allergic:** Syndrome of abdominal pain, fever, chills, nausea and vomiting anaphylaxis, bronchospasm (see CONTRAINDICATIONS), **Renal:** Acute renal failure in patients with pre-existing significantly impaired renal function, decreased creatinine clearance, polyuria, azotemia, cystitis, hematuria, **Miscellaneous:** Dry eyes and mouth, gingival ulcer, rhinitis

Incidence less than 1%—Causal Relationship Unknown**

Gastrointestinal: Pancreatitis, **Central Nervous System:** Paresthesias, hallucinations, dream abnormalities, pseudotumor cerebri, **Dermatologic:** Toxic epidermal necrolysis, photoallergic skin reactions, **Special Senses:** Conjunctivitis, diplopia, optic neuritis, **Hematologic:** Bleeding episodes (e.g. epistaxis, menorrhagia), **Metabolic/Endocrine:** Gynecomastia, hypoglycemic reaction **Cardiovascular:** Arrhythmias (sinus tachycardia, sinus bradycardia), **Allergic:** Serum sickness, lupus erythematosus syndrome, Henoch-Schonlein vasculitis, **Renal:** Renal papillary necrosis

*Reactions occurring in 3% to 9% of patients treated with *Motrin*. (Those reactions occurring in less than 3% of the patients are unmarked)

**Reactions are classified under "*Probable Causal Relationship (PCR)*" if there has been one positive rechallenge or if three or more cases occur which might be causally related Reactions are classified under "*Causal Relationship Unknown*" if seven or more events have been reported but the criteria for PCR have not been met

Overdosage: In cases of acute overdosage the stomach should be emptied The drug is acidic and excreted in the urine so alkaline diuresis may be beneficial

Dosage and Administration: Rheumatoid arthritis and osteoarthritis. Suggested dosage is 300, 400, or 600 mg t.i.d or q.i.d Do not exceed 2400 mg per day Mild to moderate pain 400 mg every 4 to 6 hours as necessary

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Dandruff and Seborrheic Dermatitis

Russell W. Eyre, M.D., Claude S. Burton, M.D. and J. Lamar Callaway, M.D.

"Oh, no. He's scratching his head. He must have dandruff." Advertisers have equated bad breath, body odor, and dandruff with social unacceptability. They assure us that just a few short minutes spent each day in the company of their products will assure us all of an active social life and plenty of friends.

Everyone has dandruff to some degree. We all shed our skin every forty-five days. People with dandruff just shed their skin at a faster rate and in larger, visible, clumps of cells. Each square inch of a normal scalp sheds about 70,000 cells a day. Scalps with dandruff shed twice this amount. Individual cells that are shed are much too small to be seen with the unaided eye. They're invisible. However, in dandruff these cells don't fall off individually. Bonds that normally break and allow cells to be shed singly hold fast. The result is the familiar snowflake scale of dandruff.

When inflammation or redness occurs with dandruff the diagnosis is usually seborrheic dermatitis. This is one of the most common skin diseases seen by the dermatologist. From two to four of every hundred people have some form of seborrheic dermatitis. The term seborrhea comes from the Latin, sebum, which means tallow or lard, and the Greek, rhoia, which means to flow. Seborrheic dermatitis refers to an eruption that occurs in those areas of the body rich in oil, or sebaceous glands. These glands are abundant on the scalp, face and central chest. Patients with seborrheic dermatitis often have a glistening or shiny appearance to their scalp and symmetrically distributed orange-yellow scaling patches. These patches are most commonly found scattered over the scalp, along the scalp margin, in the eyebrows and eyelashes, over the central chest, in the ears, along the sides of the nose, and in the nasolabial fold.

The cause of seborrheic dermatitis is unknown. Stress, overwork, and infrequent shampooing may worsen the dermatitis. During both World Wars great numbers of troops were affected and some were even incapacitated by secondary infections of their dermatitis. It is not uncommon for a patient who has just had a heart attack to also experience an attack of seborrheic dermatitis. Students at examination time often experience increased scaliness. Infants and adolescents are commonly affected with seborrheic dermatitis; the sebaceous glands are very active at these times. Patients with Parkinson's disease (a neurological disorder) and patients with spinal cord injuries (especially quadraplegics) frequently have severe seborrhea even when they shampoo often. Treatment of Parkinson's patients with L-dopa, a chemical they lack, usually improves their seborrheic dermatitis.

It was thought that because many of the conditions associated with the dermatitis are also associated with an abnormality of sebaceous gland activity that the sebum must play some role in causing the dermatitis. However, the greasy appearance is not due to increased amounts of sebum produced. The sebum is just trapped in the abundant scales. There is an increased proportion of free fatty acids in the sebum but these acids are secondary to increased amounts of bacteria that digest triglycerides into free fatty acids. The increased bacteria are probably also just trapped in the scales because even if the bacteria are killed with antibiotics the dermatitis remains. Yeasts, especially Pityrosporum ovale, have been implicated as a cause of seborrheic dermatitis. There are increased numbers of these micro-organisms on the scalps of patients with seborrheic dermatitis but normal scalps have these yeasts as resident flora, and treatment that reduces the number of these yeasts does not necessarily improve the dermatitis.

Psoriasis may be confused with seborrheic dermatitis but the scales of psoriasis are generally thicker and occasionally the underlying scalp bleeds when the scales are removed. Besides the scalp, psoriasis is found mostly over joint surfaces while seborrheic dermatitis is distributed in body folds. Sometimes it may be impossible to distinguish between psoriasis and seborrheic dermatitis. A hybrid term, "sebopsorias," has been coined to describe this condition. Ringworm of the scalp may also mimic seborrheic dermatitis. The correct diagnosis is made by examining the scales under a microscope or culturing them. Usually there is hair loss with a fungal infection of the scalp while hair loss is not a feature of dandruff, seborrheic dermatitis or psoriasis.

No one except "Dr. Guillotine" ever cured seborrheic dermatitis. It is a lifelong condition marked by remissions and exacerbations. There are several effective treatments available which if used regularly will diminish the scale to invisible levels. Rarely a drug such as cimetadine, chlorpromazine, gold, or arsenic causes seborrheic dermatitis. Stopping the drug will cure the dermatitis.

The first choice of treatment is an anti-dandruff shampoo. There are several types available. One type contains chemicals that help to break the bonds that hold scales together. These keratolytic, scale dissolving agents, such as sulfur and salicyclic acid, are found in Sebulex, Ionil, and Vanseb. Shampoos that inhibit rapidly proliferating epidermis such as Selsun Blue, Exsel, Zincon, Head and Shoulders, and Dannex are also effective. However, those that contain selenium may cause diffuse hair thinning especially if used for long periods of time. Tar shampoos such as Ionil-T, Sebutone, Vanseb-T, Zetar, and T-gel decrease inflammation and are becoming more cosmetically acceptable. When thick scales are present the overnight application of an oil or grease may help to loosen the scales. We recommend olive oil, mayonnaise, vaseline, baby oil, Baker's P and S, or Dermasmoothe FS.

Seborrheic dermatitis is extremely responsive to steroids. In the scalp, stronger steroid solutions such as Syunalar, Valisone, Diprosone, or Lidex may be used intermittently. On the face or chest, only milder steroids should be used to avoid complications such as adult acne, stretch marks and thinning of the skin. We use 1% hydrocortisone, Westcort, Tridesilon, or Hytone. On the eyelids Blephamide solution which contains sulfur and a mild steroid is effective but the patient should be followed by an ophthalmologist to monitor steroid side-effects in the eye such as cataracts and glaucoma. One otolaryngologist collects ear wax removed from normal patients and resuspends it in a glycerin solution which he dispenses for seborrheic dermatitis of the ear canal. If the dermatitis becomes secondarily infected a course of oral antibiotics may be required.

With proper care and dermatologic consultation all but the most difficult patients may be rendered free of dandruff and able to wear dark sweaters without fear of social embarrassment or snowflakes on the shoulders.

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Patsy Caudle

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TOXIC ENCOUNTERS

'Tis The Season To Do Folly: Horrendous Holiday Horticultural Happenings

Ronald B. Mack, M.D.

• This is a good time to remind you that many lovely Christmas plants are toxic. Little people are especially attracted to their bright berries and leaves — an attraction with potentially fatal consequences.

I would suspect that most people look forward to the Christmas-New Year season with great joy. To the health care professional involved in emergency care, however, this time of year is coated not with tinsel, but with a small amount of dread. Bah humbug, you exclaim! Just think of it, how many situations during the Holidays can you name that portend potential disaster for the wee folk for whom Christmas is the event of the year.

Accidents increase in children whenever there is a change in routine, e.g., during vacations, house renovation, illness or death in the family, birth of a sibling, just to name a few. This being the case, the holiday season brings an incredible number of changes for the young investigator-taster such as an increase in *visitors* (and their medicines), an increase in *visits* (to homes with many, many "goodies" to sample including cookies; cakes; household cleaning, polishing and sanitizing agents; medicines; etc). Remember that Grandma's house is one of the most dangerous sites in a pre-school child's environment, accident-wise, particularly involving drugs of a cardiovascular nature such as digitalis compounds, antihypertensives, cardiac rhythm regulators, etc. What about the visits to one's father or mother who no longer shares the family home because of separation or divorce; plenty of opportunity there to get into potential toxins now that the dwelling no longer is "poison proof" on a continuous basis. The season brings with it a sharing of gifts — lots of new stuff entering the house — Christmas tree; ornaments; tinsel; toys to swallow and stick in your eyes, ears, nose or throat, or other orifices that I would rather not mention; plants of the holiday season and of course, in many homes, more alcoholic beverages on display, ready for dispensing to visitors or self. Gosh, but it's scary to think of all this — notify the Grinch and call the whole darn Holiday off — it does not seem to be worth it. Do you recall what Ebenezer Scrooge said in Charles Dickens' classic *The Christmas Carol:* "out upon Merry Christmas! What's Christmas-time to you but a time for paying bills without money; a time for finding yourself a year older, but not an hour richer. . . . If I could work my will, every idiot who goes about with Merry Christmas on his lips should be boiled with his own pudding and buried with a stake of holly through his heart."

One area of toxicology that does seem to increase in the Joyous Season is the ingestion of plant material indigenous

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Illustrations by Ernest Craige, M.D.

to the holidays. Therefore, I am submitting these words to those health care practitioners out there in the real world who may be confronted with people, big and small, who ingest berries, leaves, flowers, stems of holiday plants.

Poinsettia: The poinsettia was introduced in the United States in 1828 by Joel R. Poinsett, then U.S. Ambassador to Mexico. This plant, one of the most typical symbols of the Yuletide, suffers from bad public relations. Every Christmas the debate resumes about this beautiful plant's toxicity; the complete answer is still not in. However, a reasonable judgment concerning its potential dangers can be made on the basis of its history. Yes, I know that the literature says that in 1919 a child in Hawaii died after eating poinsettia leaves. So what, must the plant be maligned forever? The plant has been punished enough. During those same years one of my Dad's cousins blew away a competitor during the Prohibition territory wars and he was forgiven by a sympathetic judge in Chicago (the best that money could buy). The plant that killed the child in Hawaii was alleged to be an indigenous wild poinsettia plant. The modern day plant is a hybrid with properties considered by most authorities to be non-lethal. Now it is true that the plant contains a milky, white sap in the leaves, stems and flowers (AKA bracts) and this sap can be very irritating to the eyes, skin and gastrointestinal tract. In susceptible individuals an acute contact dermatitis can occur from contact with the sap but this event is not common. Ingestion of the leaves or red bracts can cause vomiting, diarrhea and abdominal pain. The leaves are quite bitter and most little people probably would not swallow them in quantity.

A few years ago one of my sons, at a fraternity Christmas party, allegedly consumed two poinsettia leaves as an act of bravado to impress his fraternity brothers and assorted lady friends. It is alleged by competent (?) witnesses (some of whom were alleged to be acutely mind-altered at the time) that there were no sequellae following this ingestion. My son did not tell me about this impromptu experiment until a year later. After all, he does not know what I do for a living, do any of your children really know what your work consists of? The funny thing is — like most of our own younguns — he never listened too well to parental requests; if I would have asked him to swallow the leaves as a research project for me he probably would not have done so.

In the recent literature there is an article[1] describing an infant who chewed on a poinsettia leaf and acquired burns of the buccal mucosa. I suspect this phenomenon is not very common, but should be noted. The treatment is symptomatic if the patient gets involved with this plant. Gastric decontamination is probably indicated if the patient has not vomited already.

Mistletoe: This bit of flora conjures up warm feelings of closeness that are such a part of the Season; it makes us think of the kisses that you gave or received while standing under this plant or the kisses you wished you had given or received. However, mistletoe is a bad actor, poison-wise. We should have been able to predict its evil behavior — in Norse mythology, the mistletoe was the only living thing that did not swear an oath not to harm the great Balder (remember him?) who was the god of beauty and light. Balder was the son of Odin, the number one Norse god. Loki, a feared enemy of the god, slew Balder with an arrow made of mistletoe. Heaven forfend — I never knew anyone who died as a result of mistletoe but I did know an intern mate of mine who got the stove-top stuffing beat out of him

for kissing a nurse (who was betrothed to another) while both happened to be under the mistletoe.

The mistletoe is really nothing but a parasite — literally. This plant is a parasite of the oak and other trees and contains two amines that are potentially very toxic indeed — tyramine and beta-phenylethylamine — and ingestion *can be fatal*. All parts of the plant contain these amines, but it seems to me that small children would be most attracted to the berries which are pea-sized and fleshy white. These toxic amines stimulate smooth muscle resulting in hypertension, bradycardia and increased uterine and intestinal motility. The poisoned patient can experience nausea, vomiting, diarrhea and severe abdominal pain. The most severe and therefore potentially lethal consequences of mistletoe ingestion relate to the cardiovascular system, i.e., vasoconstriction and cardiac arrest; delerium and hallucinations and seizures can also occur. Animal studies have shown that the amines from the mistletoe plant produce the same effects as an injection of the cardiotoxin from cobra venom. Mistletoe extracts are sold in health food stores as it is one of the oldest and most widely used herbal remedies. It has been recommended by "nature lovers" as a treatment for asthma, epilepsy, pregnancy (has been used historically as an abortifacient), infertility as well as an aphrodisiac (it doesn't work). In a recent report in the British literature,[2] mistletoe tea ingestion was thought to be responsible for a case of hepatitis.

Remember that this plant can kill if ingested — early gastric decontamination is certainly indicated even if the child only ingested a few berries (more than 1 or 2 or 3?, how can you tell if the history is accurate? Protect the patient and yourself). Monitor the patient's cardiac status and potassium status as you would a patient who ingested digitalis-like drugs.

Christmas Holly Berries: No question about it, holly berries look good enough to eat and people do. The bright red berries (some are black) are so attractive that some children find them hard to resist but they can result in poisoning, sometimes very serious indeed — including death. Holly trees grow up as either male or females (isn't that sweet); therefore only half the trees bear the poisonous fruit and I can't figure out which half — oh well, that's my problem. Are there trees that can go either way? (Hush boy, this is a family magazine.)

Ingestion of the leaves (rare because they have many sharp spicules) or most particularly the berries can result in almost immediate mild to severe nausea, vomiting, diarrhea and abdominal pain. The loss of fluid can be so remarkable as to produce serious fluid balance problems. Some authors claim that holly berry ingestion can cause CNS depression including coma and death but the data are soft. The exact toxin contained in the holly is not that well defined but some authors state that the culprits are theobromine, saponins and triterpenes. It seems that children are particularly sensitive to the irritant gastrointestinal action of the saponins. Apparently small amounts of the toxin contained in the holly berries can stimulate the CNS but large doses act as depressants. If a child ingests more than 2 or 3 berries it is probably helpful to empty the stomach and administer charcoal. It is not necessary to induce emesis if the patient has already vomited enough to empty the stomach. It has been estimated that the ingestion of 20-30 berries may be fatal to a small child.

Jerusalem Cherry: This beautiful decorative plant with abundant red or yellow cherry-sized fruits is especially popular around the Christmas Season. The fruit can resemble those delectable small cherry tomatoes that all real salad-lovers crave. Do not be misled, these wonderful looking things are potentially very toxic to an unwary ingester. Both the leaves and bright berries are considered very poisonous. The toxin contained in the berries is a *solanine*, specifically solancapsine which is a toxic glycoalkaloid. Relatively small doses of solanine are very irritating to the GI tract causing vomiting, diarrhea and abdominal pain. The initial adverse clinical feature is an irritation of the oral mucosa and a scratchy throat. Large doses can result in respiratory distress, bradycardia, cardiac depression, cardiovascular collapse and even death. Some patients experience mydriasis, fever, confusion, dizziness and excessive salivation. Death is rare but has been reported. Some people make a jelly from the cooked ripe berries; no thank you. I prefer Smuckers, in spite of the name. The treatment is standard and symptomatic. If the patient has not vomited, induce emesis and administer activated charcoal. Some patients act as if they have been poisoned by atropine and should be managed accordingly.

It seems reasonable to suggest to parents who seek guidance for a child who has ingested a poisonous plant to suggest that the mouth be washed out with water and then to administer ipecac syrup if all the proper conditions are met. The administration of activated charcoal appears to be quite helpful in the management of poisonous plant ingestions.

What can we learn from all of this? Eliminate the Holidays — no festive plants, no gifts, nothing or at best give children an orange in their Christmas stocking and bad children lumps of coal. By the time I was eight years old I had accumulated enough coal to heat Cleveland for a week.

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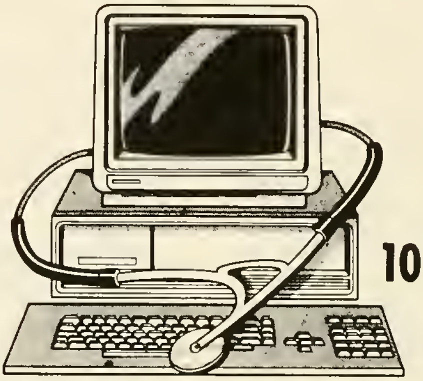

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CAROLINA HISTORY

An Account of How Deep Hypothermia Was First Used to Increase the Safety of Open Heart Surgery

Will C. Sealy, M.D.

• How a five-year-old "blue baby" girl in the right place at the right time lived to grow up and produce her own healthy children.

TWENTY-FOUR years ago, a five-year-old girl, blue, breathless, and having frequent falling out spells, was brought to Duke Hospital seeking help. A series of examinations showed that her illness was caused by two heart defects, one a partial blockage of the vessel connecting the heart and lungs, and the other a large hole between the two ventricles. This caused the volume of venous blood circulating in the lungs to be reduced and shunted to the left ventricle, markedly diluting the arterial blood, resulting in her life-threatening problems. The patient was a "blue baby" and her heart disease was called the Tetralogy of Fallot. After careful review of all examinations, the decision was made that the best and safest treatment would be to open her heart and correct the defects, rather than to do a shunt operation that would only partially relieve her symptoms for a short time. This decision was influenced by the recent development by the Duke cardiac surgeons of a new method for opening the heart using deep hypothermia controlled with a pump oxygenator. This is an account of how this new method, a landmark event in open heart surgery, was devised at Duke and then used in its first clinical application to cure this sick child of her congenital cyanotic heart disease.

In the mid 1950s, open heart surgery could only be done using one of two methods. The first,[1] surface-induced mild hypothermia (temperatures in the esophagus of 32-34°C) used alone, allowed only five to seven minutes of open heart time, since the circulation had to be stopped in order to open the heart. The second,[2] utilizing the heart-lung machine, allowed about thirty minutes of safe time to work within the heart. In 1954, when I began to consider these two methods, neither of the two appealed to me as being safe or practical. It seemed logical, however, that the two methods, when combined, would give the advantages of both, although no other surgeons at that time were deliberately doing this. My reasoning was that the mild hypothermia would reduce the oxygen demand as well as other metabolic requirements to the point where a low-flow perfusion by the then available heart-lung machines would supply the needs.

In using the combination of mild hypothermia and extracorporeal circulation at Duke,[3] the patient's temperature was reduced to about 32°C (90°F) by immersion in a tub of ice water. This required 60 to 90 minutes. Next, the patient was connected to a pump and bubble oxygenator using flows of about 2500 cc for an adult. The open heart operation was then done. When the operation was completed, the patient was disconnected from the heart-lung machine and rewarmed with hot water bottles or immersion again in a tub, but mostly this occurred with heat generated by the patient's own metabolic activity, an added stress to an ill patient. Although this new method was still time limited, it afforded us a practical and safe method for correcting most simple congenital cardiac defects.

As the members of the cardiac surgical team watched the patients during the long rewarming process, the obvious solution to this awkward and dangerous step soon became evident: Use the heart-lung machine to rewarm the patient. The first attempts to do this were with the plastic tubing added to the arterial line of the pump, passing the extra tubing through a trough of warm water. This failed. The thick plastic tubing was grossly inefficient as a heat exchanger. This problem was solved by Ivan Brown, Wirt Smith and Allan Lesage. Wirt Smith had a background in engineering and was then a fellow with Ivan Brown in the Duke blood bank. Allan Lesage ran the thoracic surgical laboratory and operated the heart-lung machine. Long thin stainless steel tubes replaced the plastic ones. These were satisfactory. Once we established that warming could be easily done, the next step also became obvious: Cool the patient by allowing the blood entering the patient to pass through steel tubes immersed in cold water. This handmade device was efficient and gentle on the blood, and marked the first time a heat exchanger had ever been used with a pump oxygenator. The method is called core cooling in contrast to surface cooling that occurs with immersion.

The next episode in this story illustrates what a large role

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luck can play in solving a surgical problem. At the time we found we could regulate temperature during heart-lung bypass with a crude heat exchanger, it was close to the Christmas holidays. Ivan Brown's family lived in Lockport, New York, a town close to the Harrison Radiator Division of General Motors. While visiting his family over the holidays, Ivan met Mr. W. D. Emmons, the Chief Engineer at Harrison. Ivan, who was one of this country's leading authorities on blood banking, seized this unique opportunity. With engineering capability of one and blood handling knowledge of the other, an efficient heat exchanger for a heart-lung machine was planned and then fabricated.[4] The instrument consisted of multiple highly polished stainless steel tubes for blood transport, surrounded by a water jacket for circulating water. The heat exchanger had to be extremely efficient to be practical. On an adult at the flow rates of 2500 ml per minute the perfusion was about half that employed for a 70 kg adult today. With high perfusion rates, even a crude heat exchanger will work. With this machine placed in the arterial line, the temperature of the blood was regulated by water circulating in the jacket at a controlled temperature (figure 1). A modification of this instrument is now part of all heart-lung machines, functioning not only to induce and revert hypothermia, but to maintain temperature at normal levels, even to raise it to hyperthermic levels in certain special situations.

One problem among the many that we were concerned about was the likelihood of the heart developing ventricular fibrillation when made cold. At that time there were no manufactured devices for correcting this arrhythmia, only locally fabricated paddles plugged directly into the 120 volt lighting system. This anticipated problem with the heart was discussed with Jerome Harris, Duke's Pediatric Cardiologist. On his advice, Glenn Young, Doris Merritt and I worked out a heart stopping (cardioplegic) solution containing potassium, magnesium and prostigmine, that would effectively revert ventricular fibrillation.[5, 6] The laboratory studies were completed before we were aware of Melrose's experiments.[7]

In addition to controlling the arrhythmia, cardioplegia was found to permit cross-clamping of the aorta and thus interrupting the coronary blood flow for a short time, because lack of muscle contraction as well as the hypothermia reduced the metabolic demands of the heart. With this method, an intracardiac operation could be done, in part, in a relatively dry field.

With our low flow bubble oxygenator and mild core-induced hypothermia and cardioplegia, a large group of patients was successfully operated upon. This was reported before the Southern Surgical Association,[8] and marked the first account where these three modalities were deliberately and knowingly combined.

Following our success with the use of the heat exchanger to attain mild hypothermia, logically the next step was the extension of the limits to profound hypothermic levels (below 18°C), which we had good reason to believe would increase the safety of the pump oxygenator, allow more

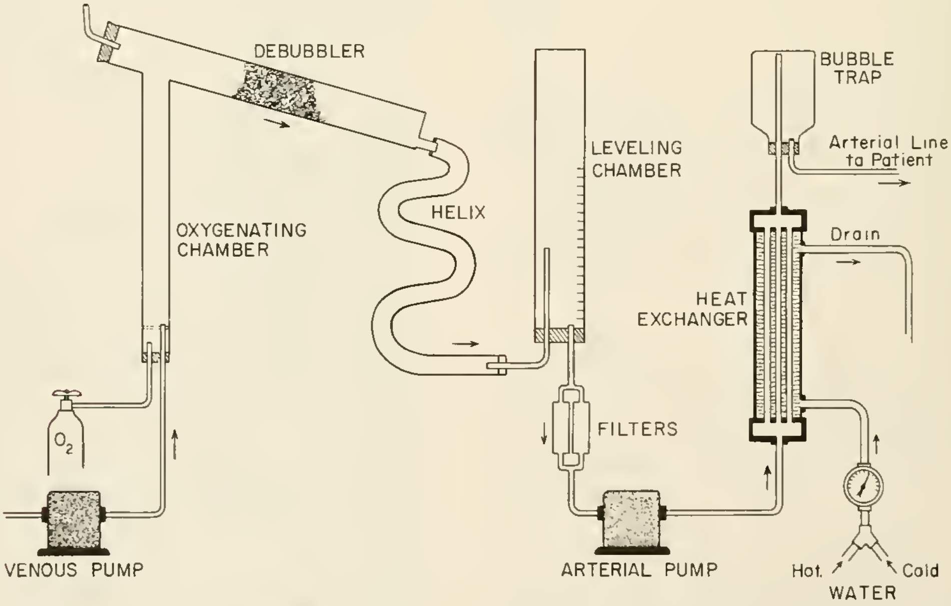

Figure 1. *This is a drawing of the extracorporeal system used for core induction for both mild and profound hypothermia. In large individuals, two heat exchangers were placed in series for the latter. In mild and moderate hypothermia, water from the hot and cold water lines was used, passed through a mixing valve. For deep hypothermia, a large bucket of ice water and a small pump were placed on the system. The oxygenator was fabricated from dairy equipment. The de-bubbler was a Tuffy sponge sprayed with defoaming material. Nearly all currently used oxygenators are modifications of this system, the original DeWall-Lillehei oxygenator.*

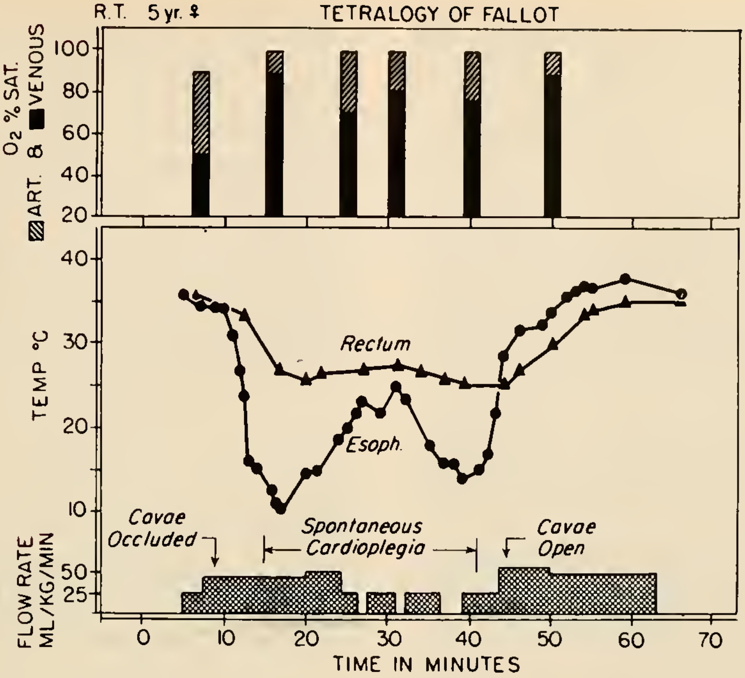

Figure 2. *A record made from observations at operation in the patient described in the text. In the panel above are the percent saturation of samples of arterial and venous blood. In the lower panel, rectal and esophageal temperatures are plotted. There were three short periods of circulatory arrest, as shown in the lower panel. In many patients during deep hypothermia, the heart either went into standstill or into ventricular fibrillation and then standstill.*

time to correct complicated intracardiac problems and, in special situations, allow periods of circulatory arrest but with perfusion continuing for most of the operation. Allan Lesage and various laboratory Fellows from thoracic surgery, many from Japan, carried out hundreds of experiments proving the validity of using profound hypothermia.[9] Among their many observations, they noted temperature differences in various organs, oxygen consumption, acid base balance, tolerance of the cold heart to ischemia, and the times of tolerable circulatory arrest at temperatures below 18°C. In these studies, circulatory arrest during deep hypothermia was found to be safe for 30 minutes and up to an hour with increased risk, the brain, of course, being the most sensitive indicator. Using this laboratory information, as well as our experience with mild perfusion-controlled hypothermia in patients, we then felt justified in the use of deep hypothermia for complex intracardiac operations. Tetralogy of Fallot, at that time, was the greatest challenge in open heart surgery. It was a time consuming, high risk procedure with a high morbidity rate from heart block if hurried and working in the heart in a pool of blood. One clinic reported a 32 percent mortality rate in a cyanotic group of patients with Tetralogy of Fallot.[10]

Glenn Young was the surgeon of the five-year-old seriously ill child with Tetralogy of Fallot noted in the introduction. She underwent closure of the ventricular defect and removal of the pulmonary obstruction using an oxygenator, pump and heat exchanger as shown in figure 1. Her body temperature (as measured in the esophagus) was reduced to 7°C, and three periods of circulatory arrest were used, so that the sutures to close the defect in the septum could be correctly placed avoiding the His bundle and thus preserving atrioventricular conduction. In figure 2, the periods of circulatory arrest are shown, as well as the marked decrease in oxygen utilization demonstrated by the narrowing of the arteriovenous oxygen differences. Note that for the most part perfusion continued throughout the operation. No problem occurred in the immediate or late postoperative period. The patient has led a normal life since the operation and is the mother of two normal children. Following this first operation, fifty additional patients were operated upon.[11]

About this same time, other surgeons, particularly Drew[12] at Westminster Hospital in London, were using profound hypothermia to insure the safety of open heart surgery. Although he used perfusion induced cold, his method was cumbersome. It required two cannulae in the right and two in the left side of the circulatory system, with a second pump to perfuse the lungs which oxygenated the blood, since there was no oxygenator in his system. Circulatory arrest was mandatory for an intracardiac operation. The report from Bjork's[13] experience with the Drew method where a high percentage of patients had brain damage confirmed the dangers of circulatory arrest for long periods. Bjork's report was influential in curbing the interest in deep hypothermia at that time, even though he did not use what is now the accepted technique.

The Duke neurosurgeons became interested in deep hypothermia as a method of circulatory arrest for easing the problem of exposure to difficult neoplastic and vascular lesions. This first application in neurosurgery was by Barnes Woodhall and the author.[14] The record from one of these patients is shown in figure 3. The measurements of brain temperature made during these operations emphasized the important fact that the brain cooled more slowly than the esophagus. This may have been a factor in some of the early adverse reports about deep hypothermia and circulatory arrest, the latter occurring before the brain was cooled to safe levels.

The recognition of the importance of our studies came when the author was invited to be one of three principal speakers at an international symposium on hypothermia sponsored by the University of Paris and held in 1961 in Paris at UNESCO.[15]

Following our successes in the late 1950s, this method was abandoned at Duke and nearly every other clinic in the United States, only to be revised and returned to use in the late 1960s and early 1970s, due to the efforts of Mohri, now of Japan, who was working at that time with Al Merendino in Seattle.[16] Their method, similar to our early method for mild hypothermia,[8] was to use 18°C. The operation, however, was done with the circulation interrupted. The pump oxygenator was used to rewarm the patient. Soon this technique was abandoned by most and core cooling substituted, just as we had originally advised.[17]

There were several reasons for the temporary abandonment of deep hypothermia for open heart surgery. In our early reports we recommended esophageal temperatures of 7 to 10°C. Now we know that this was lower than needed, and the metabolic gains from this temperature did not compensate for the time needed to reach this level. For example, the attainment of temperature drops from 17°C to 7°C required a much longer time than reducing the esophageal temperature from 37° to 17°C, due to the restrictions of the temperature levels of the water in the heat exchanger acting as the coolant. About this same time, pump oxygenators became more efficient and thus one of the reasons for using hypothermia was no longer as important as it once was. The use of immersion-induced hypothermia by Mohri and Merendino had the great advantage of more uniform cooling of all structures and avoided the slow rate of cooling of the brain which was an unrecognized problem with others who used core cooling. The surgeon did not delay circulatory arrest long enough to allow the brain to cool as shown in figure 3. The 18° to 20°C esophageal temperature can occur well before the brain is cool enough to allow circulatory arrest or, as needed in special cases, interruption of the blood flow to the brain. Just as happened in our initial experience with mild surface-induced hypothermia, core cooling and rewarming with the

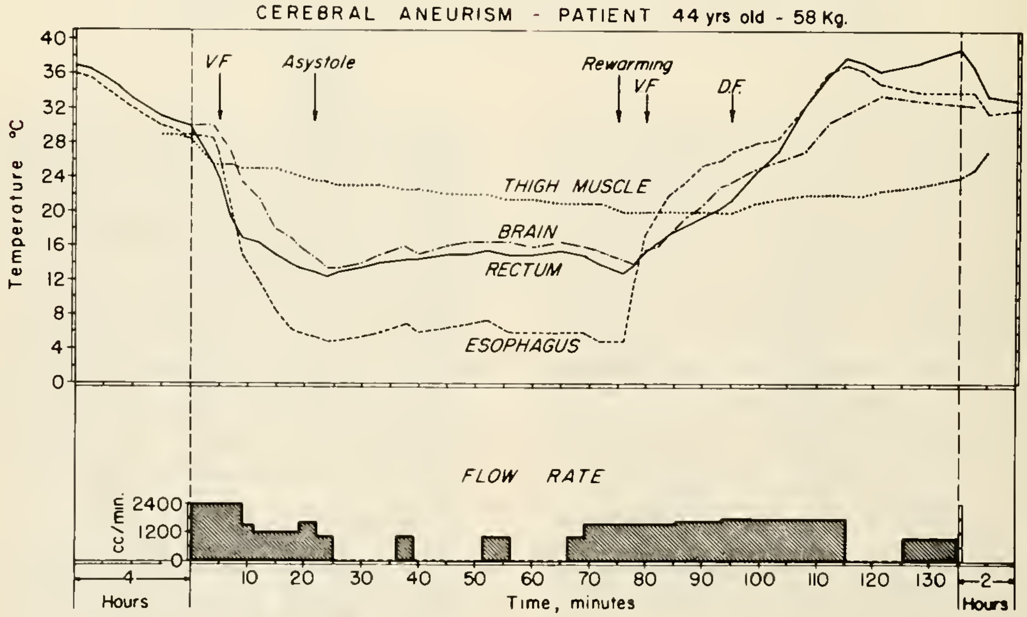

Figure 3. *This is the record made from a neurosurgical patient operated upon for a cerebral aneurysm by Barnes Woodhall. The temperature gradients shown in the upper panel emphasize the lag in the cooling rate of the brain as compared with the esophagus. Note the cooling and rewarming curve of the muscles of the thigh. The lag reflects to a great degree the difference in the rate of blood flow between muscle and other areas recorded. The flow rates and periods of circulatory arrest are shown in the lower panel. VF, ventricular fibrillation. DF, defibrillated.*

pump oxygenator were soon almost universally employed, not only in children but in many adult operations. During deep hypothermia, only a small flow rate is required.

The account of this series of events merits attention for two reasons. First, the story is a landmark event in the evolution of methods that have increased the safety of cardiopulmonary bypass and thus open heart operations. To me, the second is the most interesting. A group of doctors with free communication and mutual respect pooled their various talents and accomplished what turned out to be a paradigm of surgical research, that is, the taking of information accumulated by more basic investigators and, after careful laboratory testing of the applications of these basic principles, applying them to establish new and improved methods of treatment that were a major factor in making heart surgery safe.

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A Report on the Use of a Family Nurse Practitioner to Reduce Industrial Health Care Costs

C. J. Dellinger, M.D., Judy L. Zentner, F.N.T.C., and Wayne Annas

• *A furniture company hired a family nurse practitioner to perform tests, counsel employees, care for minor on-the-job injuries. The results, in dollars and cents, are presented here.*

IN 1982 a local furniture company employing 700 persons was struggling with spiraling health care costs as were other industries across the nation. Its approach to reduce health care costs was a novel experiment, the results of which are reported here.

The company was required by OSHA to check audiograms annually, necessitating the employment of trained personnel. It decided to use a Family Nurse Practitioner (FNP) to do the audiograms plus health screening and review of daily illness and injury situations.

Method

The tasks delegated to the FNP were submitted on her application to the State Board of Medical Examiners. They fell into four areas: 1) audiometry and dosimeter studies for noise exposure, 2) on-the-job emergencies, 3) preventive measures, and 4) health care counseling. She was required to keep medical records which were reviewed weekly by the sponsoring physician.

Audiometry testing had previously been performed under contract by an outside firm. In the period studied, the FNP performed 450 studies. Dosimeter studies involved the documentation of noise levels in different work areas.

On-the-job injuries were seen first by the FNP whenever possible. These consisted of sprains, lacerations, back strains, splinters, and foreign bodies in eyes. During the study period, 800 such encounters were reported. These encounters sometimes included multiple visits by the same persons. Surgical problems were referred directly to a general surgeon bypassing the hospital emergency room and its added expense.

Preventive medicine included updating tetanus toxoid immunizations, flu vaccines, pre-employment physical exams, and annual multiphasic testing.

Health care counseling involved dealing with problems the employees encountered such as upper respiratory infections, urinary tract infections, high blood pressure, marital problems, and alcohol problems. Throat cultures were performed when needed on persons complaining of sore throat. The results were reported to the employee and his or her physician. If the employees were patients of the sponsoring physician, the FNP treated the patient according to the protocol outlined in *Patient Care Guidelines for Nurse Practitioners*.[1] Employees who had other physicians were referred to their own physician for treatment. Urinary tract infections were treated the same way. Conditions such as consistently elevated blood pressure, diabetes, anemia, hematuria, hernias, and thyroid nodules required referral to a physician.

Results

The results of one year's experience are listed in table 1.

The audiometry testing was valued at $8.00 per test by a health testing firm in its contract. Having the Family Nurse Practitioner perform 450 tests represented a saving of $3600. Dosimeter was also valued at $8.00 by outside contractors, a saving of $160 on the 20 measurements.

The possibly-job-related encounters represented 800 visits by employees, including repeat visits. Eye complaints accounted for 100 visits. The largest number of visits was for musculoskeletal complaints, such as sprains and backaches. Trauma and counseling or education accounted for 150 visits each. Sutures were removed from eight persons who had had lacerations repaired. Two minor lacerations were repaired with steristrips.

Preventive maintenance activities accounted for 671 visits.

The largest group of encounters was for health care counseling which accounted for 2330 visits. These visits were for many different problems such as anemia, upper respiratory infections, blood pressure evaluations, rashes, follow-up on diabetes, vaginitis, emotional problems, allergy injections, and counseling about over-the-counter drugs. In all instances when the problems fell out of the expertise or scope of protocol of the FNP, the employees were referred to their own physicians or the sponsoring physician.

Based on fees from the Industrial Commission for the

State of North Carolina, the 800 possibly-job-related visits represented $16,000. Recognizing that many of the workers would not have sought medical care for their injuries, we used the actual claims costs to figure savings. The table below illustrates the claims experience during the three years under study:

Year	*Number of Claims*	*Cost*
1981	108	$33210
1982	58	34272
1983	47	25293

Assuming that without the FNP the worker's compensation claims for 1983 would have remained equal to the average of 1981 and 1982, or $33,741, this actual claims cost of $25,293 represents a savings of $8448. Besides the reduction in money spent on claims, there was also a reduction in the number of claims.

Using the fees for worker's compensation for health care counseling gives a total of $41,932.00. Estimating that only 50% of these employees would have sought medical help without the program brings the savings to $20,966.00.

Preventive maintenance represented a savings of $9,275.00 using a similar fee scale. Realizing that these savings would probably be real for the industry, the figures were not adjusted.

There were some interesting observations on insurance claims filed during the two fiscal years the program was in existence as illustrated in the table below.

Year	*Employee Claims*	*Dependent Claims*
1981	346	221
1982	332	234
1983	282	313

Fiscal year 1981 was the year prior to starting the program. The study period actually covered parts of fiscal year 1982 and 1983. In 1982 there was a reduction in employee claims by 4.2% compared with 1981, and a rise in dependent claims of 5.1% for the same time. In 1983 the employee claims dropped by 22.6% compared with 1981 while the dependent claims rose 29.4% compared with 1981. The reduction in employee claims enabled the industry to avoid a 12.5% insurance rate increase for 1983 and 1984, an estimated savings of $150,000. Other furniture manufacturers in the same community *did* have a 12.5% insurance increase annually during this period. The $150,000 figure is the value placed by the company auditors.

Absences in 1983 were 6968 fewer man-days than in 1981. At $48 per day ($6/hr) this represents a savings of $41,808 to the employees in lost wages. The savings to the company by the employees being on the job are not as easy

Table 1
Patient Visits to the FNP and Their Calculated Cost

	Patient Encounters				Costs		
	Audio	Job Related	Preventive Care	Health Care	Worker's Comp Fees	Preventive Care Costs	Health Care Costs
Hematology		0		16	20.00	0.00	320.00
ENT		0		452	20.00	0.00	9040.00
Eye		100		15	20.00	0.00	300.00
Respiratory		0		42	20.00	0.00	840.00
Cardiovascular		0		610	20.00	0.00	12200.00
Musculoskeletal		315		49	20.00	0.00	980.00
Skin		75		103	20.00	0.00	2060.00
Ob/Gyn				39	20.00	0.00	780.00
G/U		0		110	20.00	0.00	2200.00
Neurology		0		28	20.00	0.00	560.00
Endocrine		0		64	20.00	0.00	1280.00
Trauma		150		33	20.00	0.00	660.00
Counseling		150		158	20.00	0.00	3160.00
Gastrointestinal		0		78	20.00	0.00	1560.00
Complete physical		0	136	0	35.00	4760.00	0.00
Health check		0	45	0	20.00	900.00	0.00
Tetanus injection		0	96	0	6.00	576.00	0.00
Blood tests		0	225	0	9.00	2025.00	0.00
Urinalysis		0		184	8.00	0.00	1472.00
Hearing	450	0		0		0.00	0.00
Flu Immunization		0	169	0	6.00	1014.00	0.00
Throat culture		0		106	6.00	0.00	636.00
Dosimeter	20	0		0		0.00	0.00
Pelvic exam		0		19	20.00	0.00	380.00
Allergy injection		0		61	4.00	0.00	244.00
Weight check		0		28	20.00	0.00	560.00
Ear wash		0		18	20.00	0.00	360.00
OTC drugs		0		117	20.00	0.00	2340.00
Suture removal		8		0	20.00	0.00	0.00
Steristrip		2		0	20.00	0.00	0.00
Totals	470	800	671	2330		9275.00	41932.00

to measure.

The table below lists the savings to either the company or the employee with the Family Nurse Practitioner.

Audiometry	$3760
Worker's compensation	8448
Preventive care	9275
Health care counseling	20966
Loss in man days (6968)	41808
Savings in insurance premiums	$150000
Total	$234257

For a more accurate total of savings it is necessary to subtract the cost of the program from the above figure. During the year 1983 the total cost of the program was $28,109.50. This figure includes the salary for the FNP, materials and commercial lab fees. The expenses are low because the FNP worked only four hours per day for the first three months of 1983. The only other expenses for the program were the consulting fees of $2500 for the physician. The net savings are listed below:

Gross savings	$234257.00
Salary and other expenses	−28109.50
Consulting fees	−2500.00
Total	$203647.50

Discussion

The furniture manufacturer has another plant in Mississippi which did not use a FNP. The employee insurance claims there rose at a rate comparable to the dependent claims at the North Carolina plant. The worker's compensation claims in Mississippi did not show a drop as they did in our plant in North Carolina. The manufacturer used the out-of-state plant as a control to evaluate the value of the FNP.

The measurable savings alone justify the use of a FNP in the industrial setting. There are many unmeasurable savings in using a FNP. Employee morale improved in the plant using the FNP. While many of the employees seeing the FNP for health care counseling may not have visited physicians' offices or other health facilities, many would, requiring an absence from work of at least half of a day. Some of these savings are reflected in the decrease in absences.

The literature does not report any such previous use of a Family Nurse Practitioner, although we know of a few similar programs in North Carolina. McClure in a paper presented at the Greater New York AOHN alluded to this expanded role for the nurse, but did not report it being put into practice.[2] Traditional roles for the Family Nurse Practitioner have been screening, counseling, and referral.[3, 4] The net savings alone prove this is a viable technique for reducing industrial health care costs.

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IN STATE

January 7-March 1
Postgraduate Course in Medical Sonics
Place: Winston-Salem
Credit: 35 hours Category I AMA
Info: James F. Martin, M.D., Bowman Gray, 300 South Hawthorne Road, Winston-Salem 27103. 919/748-4505

January 9
A Model for the Development of Gifted Children
Place: Winston-Salem
Info: Child Guidance Clinic, Inc., 1200 Glade Street, Winston-Salem 27101-2482. 919/723-2482

January 13-16
Beyond Advanced Clinical Teaching Skills
Place: Rougemont
Credit: 20 hours Category I AMA and AAFP
Info: Dr. Katherine Munning, 407 Crutchfield Street, Durham 27705. 919/471-2571

January 26
Sixth Annual Pulmonary Disease Update
Place: Greenville
Credit: 6 hours Category I AMA
Fee: $60.00
Info: Mary Valand, Box 7224, ECU School of Medicine, Greenville 27834. 919/758-5200

February 6
Grief Process in Children
Place: Winston-Salem
Info: Child Guidance Clinic, Inc., 1200 Glade Street, Winson-Salem 27101-2482. 919/723-2482

February 13
Anxiety Disorders
Place: Greenville
Fee: $30
Credit: 3.5 hours
Info: Mary Valand, Box 7224, ECU, Greenville 27834. 919/758-5200

OUT OF STATE

January 17-19
Advanced Ultrasound Seminar
Place: Orlando, FL
Credit: 14 hours Catetory I AMA
Info: James F. Martin, M.D., Bowman Gray, 300 South Hawthorne Road, Winston-Salem 27103. 919/748-4505

January 22
38th Annual Stoneburner Lecture Series: Rehabilitation Medicine
Place: Richmond, VA
Info: Kathy Martin, Box 48, MCV Station, Richmond, VA 23298. 804/786-0494

January 25-27
Winter Conference on Geriatrics
Place: Hot Springs, VA
Credit: 10 hours AAFP prescribed
Fee: $100
Info: NC Academy of Family Physicians, Box 20146, Raleigh 27619

January 26-31
Dermatology for Non-Dermatologists
Place: Cancun, Mexico
Info: Division of Dermatology, Box 3135, Duke University Medical Center, Durham 27710. 919/684-2504

January 27-February 2
Surgical Management of Malignant Disease
Place: Vail, CO
Credit: 25 hours Category I AMA
Info: Linda Mace, Box 3707, Duke University Medical Center, Durham 27710. 919/684-2033

February 3-8
Selected Topics in Internal Medicine
Place: Snowshoe, WV
Credit: 20 hours Category I AMA
Info: Cindi Easterling, Box 3108, DUMC, Durham 27710. 919/684-6878

February 3-8
Sports Medicine for the Primary Care Physician
Place: Snowshoe, WV
Credit: 20 hours Category I AMA and AAFP
Info: Cindi Easterling, Box 3108, DUMC, Durham 27710. 919/684-6878

February 16-23
Radiology Postgraduate Course
Place: Ixtapa, Mexico
Credit: 25 hours Category I AMA
Info: Jackie Wright, Box 3834, DUMC, Durham 27710. 919/681-2711 ext. 285

Letters to the Editor

More on Thyroid Nodules

To the Editor:

No one questions that fine-needle aspiration (FNA) biopsy offers a safe, inexpensive adjunct to the diagnosis and management of thyroid nodules. However, controversy exists as to when to aspirate a thyroid nodule. A traditional approach might include thyroid ultrasonography (aspirate if cystic) and then radionuclide scintiscan (aspirate if hypofunctioning). Some endocrinologists use thyroid suppression alone to treat the non-cystic, hypofunctioning thyroid nodule in patients at low risk for cancer (e.g., female patients more than 25 years old). My approach to the solitary thyroid nodule has changed.[1] I perform a FNA biopsy when I first see the patient for two reasons.

1) FNA biopsy often provides a tissue diagnosis. An experienced cytopathologist trained in reading thyroid needle aspirates can frequently make a specific pathologic diagnosis. Scintiscan and ultrasonography cannot do this. This is not to say that FNA biopsy is always diagnostic. The nature of thyroid tissue itself does not always permit the cytopathologist to exclude thyroid carcinoma from benign adenoma. Of those patients with abnormal cytologic findings (suspicious for malignancy, probably malignant, or indeterminate), only 20% have malignancy at surgery.[2]

2) FNA biopsy costs less. For the dollars spent, FNA gives more information at a lower expense. At Duke, thyroid scintiscan ($159) and ultrasonography ($143) cost more than FNA biopsy ($91). Because most patients do not have high risk factors for thyroid carcinoma (single thyroid nodule in youth, history of irradiation, clinical signs of infiltration, hoarseness, etc.) and eventually have FNA biopsy anyway, many dollars and much time are saved by performing FNA biopsy at the outset. Furthermore, since about 20% of thyroid nodules are cystic, FNA diagnoses and treats the problem in this set of patients.

Although the FNA technique is a simple office procedure, best results come from physicians who have experience with FNA biopsy. Since thyroid masses are best palpated while the patient sits or stands, I ask the patient to sit in a chair while I stand behind to palpate and fix the nodule between my index and third fingers. With the thumb and index finger of my other hand, I hold a 21 gauge needle's hub which is attached to a syringe via a connecting tube. An assistant aspirates the obturator of the syringe.[3] I usually make three passes with the needle to insure adequate sampling. Any fluid is sent to cytopathology in a heparinized Vacutainer tube. If the aspirate is "dry," I use air to force the scant amount of material within the needle onto a slide, spread the aspirate evenly with the needle tip, fix the material in 70% ethanol or with a commercial spray fixative, and send the slide to the cytopathology lab for processing. If a cytopathologist is not available locally, specimens should be mailed to an appropriate center.

If the aspirate is suspicious or frankly malignant, I proceed to surgical extirpation. For the euthyroid patient whose FNA biopsy is not suspicious and whose risk factors are low (this group makes up more than 80% of all patients with thyroid nodules), I prescribe thyroid suppression with L-thyroxine. Contrary to what Dr. Werk and colleagues recommend,[4] I do not use doses of 0.2 and 0.3 mg/day of L-thyroxine since patients often become thyrotoxic with this amount of medication. Older people do not tolerate excessive thyroid suppression. Most persons are treated with 0.1 to 0.15 mg/day. An occasional obese patient may need 0.2 mg/day. Follow-up visits (6 weeks after initiation of L-thyroxine and 4-6 months thereafter) to check serum thyroxine level and size of the nodule are mandatory. In the rare patient with a functioning adenoma, thyroxine treatment may lead to hyperthyroidism. The scintiscan in these cases demonstrates increased activity over the nodule despite continued thyroid suppression. L-thyroxine is stopped and the patient is followed.

The euthyroid patient whose nodule regresses after a few months on L-thyroxine requires no studies other than yearly thyroxine levels. Sometimes the nodule (particularly if present for years prior to suppression) does not change in size. One can be sure that the doses of thyroxine are adequate if TRH causes no rise in the serum TSH or if the 24 hr thyroidal I-131 uptake is less than 5%; the former study appears to be more sensitive. A nodule which enlarges in spite of thyroid suppression is very suspicious of malignancy. However, a sudden increase in size suggests hemorrhage into the nodule and FNA confirms this. In the absence of hemorrhage, progressive enlargement of a thyroid nodule in a patient who is adequately suppressed calls for surgical intervention.

Is the initial performance of FNA biopsy an unusual method of approach for managing a solitary thyroid nodule? Because the Mayo Clinic has extensive experience with thyroid FNA (over 5000), I recently asked Hossein Gharib, M.D., a member of the thyroid group at the Mayo Clinic,[2] how they usually evaluated a thyroid nodule. FNA biopsy is their initial study in any patient with a thyroid nodule. Their observations as well as my own have reassured me that FNA biopsy is a safe, reasonable, and cost-effective first step in the diagnosis and management of the solitary thyroid nodule.

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To the Editor:

The percentage cancer index computed by Werk et al. in the October issue of the NCMJ points up the low specificity of ultrasound and scintiscan in detecting benign thyroid nodules. Although these procedures detect nearly all malignant nodules, 80 to 90 percent of positive tests will have no malignancy.[1] The specificity of these procedures is 10 to 20 percent. The specificity of thyroid hormone suppression, defined as growth or unchanged while taking thyroid hormone, is 30 to 40 percent.[1] This means that the majority of benign nodules do not shrink in size with thyroid hormone suppression. Fine needle aspiration biopsy has a specificity of 70 to 80 percent.[2, 3] Again, specificity relates to the percentage of benign thyroid nodules diagnosed by the procedure. These reports come from medical centers where a thyroidologist takes the medical history, examines the patient, performs the aspiration and interprets the cytological specimen. These reported figures are highly biased when applied to smaller medical communities.

The primary limitation of fine needle aspiration is in the overlap of cytological characteristics of benign and malignant follicular neoplasms. Hence, all follicular neoplasms should have a large needle or cutting needle biopsy for tissue morphology. The other option is to refer all follicular neoplasms for surgical excision, but this reduces the specificity since follicular adenoma is more common than follicular carcinoma. Another problem in interpretation relates to the pleomorphic changes in follicular cells caused by cytotoxic antibodies in autoimmune thyroiditis. If the sample misses the lymphocytic infiltrate, the diagnosis will often be reported as suspicious for carcinoma. The initial thyroid profile should include thyroid antibodies, the presence of which will sway the interpretation.

The clinician who infrequently evaluates thyroid nodules needs all the diagnostic help available before arriving at a recommendation for surgical excision. An approach that has been successful for me over the past few years utilizes ultrasound, scintiscan and fine needle aspiration (FNA) biopsy (figure 1). Since cystic and hyperfunctioning nodules account for 30 percent of all solitary thyroid nodules and are rarely malignant, it is reasonable to begin with ultrasound and scintiscan. Ultrasound should precede scintiscan since cystic nodules will be nonfunctional on scintiscan, obviating the need for the latter procedure. All suspicious aspirations should be followed by large needle or cutting needle biopsy. This approach has yielded a percentage cancer index of approximately 50 percent, although admittedly I have gained proficiency in cytological interpretation. Just as importantly, 75 percent of patients are spared a surgical excision procedure.

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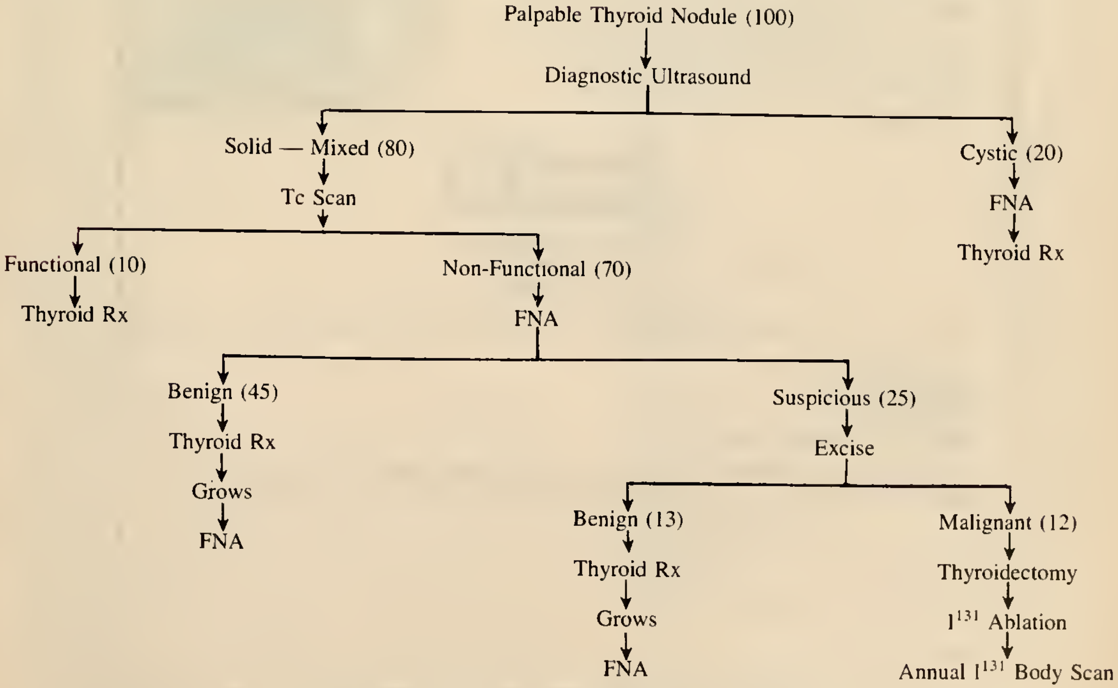
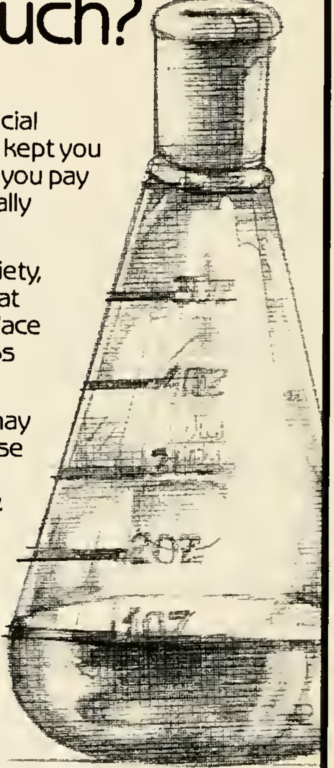


Figure 1. Algorithm for Evaluation of a Thyroid Nodule.



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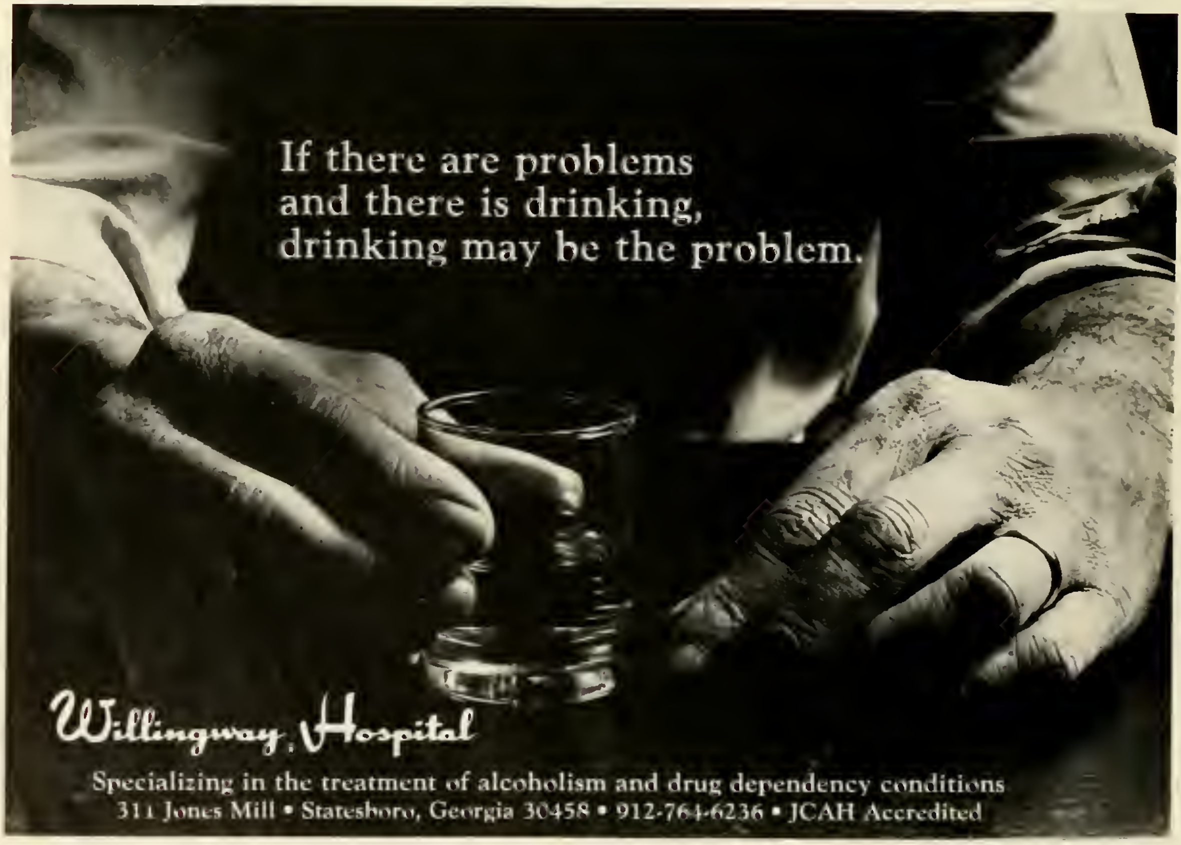

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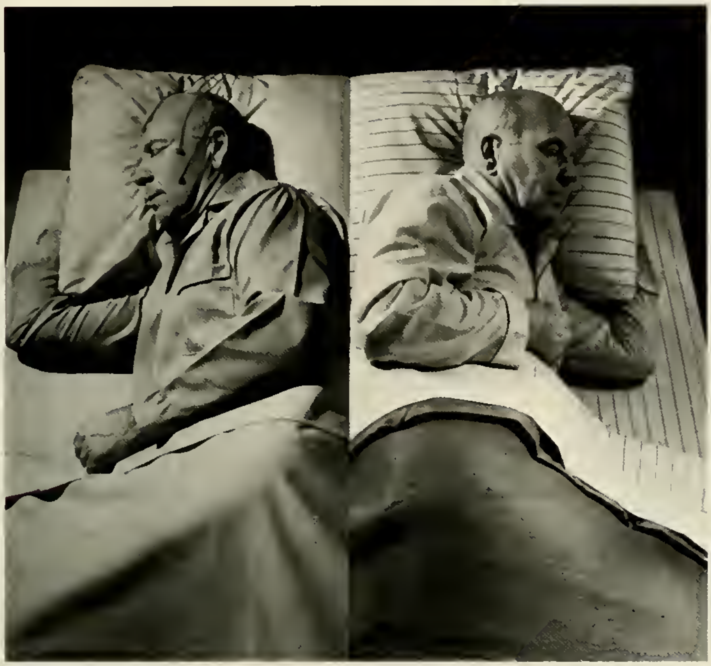

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